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In the Supreme Court
OF THE
United States

OCTOBER TERM, 1949

No. 458

COLUSA REMEDY COMPANY, Intervener,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR WRIT OF CERTIORARI
to the United States Court of Appeals
for the Eighth Circuit.

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To the Honorable Fred M. Vinson, Chief Justice of the United States, and to the Honorable Associate Justices of the Supreme Court of the United States:

Comes now Colusa Remedy Company, a corporation, (hereinafter styled Petitioner) and respectfully petitions that a writ of certiorari be issued to review the judgment of the United States Court of Appeals for the Eighth Circuit (No. 13733) which affirmed a judgment of the U.S. District Court for the Northern District of Iowa condemning, as misbranded under the Federal Food,

Drug & Cosmetic Act, various lots of a drug known as Colusa Oil; which petitioner has been distributing throughout the United States for a number of years for use in the treatment of skin diseases.

OPINION AND JUDGMENT BELOW.

The opinion of the Court of Appeals appears in the record. (C.R.-5).[1] The Findings and Judgment of the District Court appear in the record (R. 9) and are officially reported in 78 F.Supp. 721.

JURISDICTION.

The judgment of the Court of Appeals was entered on July 28, 1949. (C.R.-19.)

On October 20, 1949, an order was made by the Supreme Court (per Justice Clark) extending the time for the filing of this petition to and including November 18, 1949.

Jurisdiction of this Honorable Court is invoked under 28 U.S.C. Sec. 1254, subdiv. (1).

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[1]The printed "Transcript of Record" filed herein consists of three parts or divisions. The first is the printed record filed by appellant in the Court of Appeals (pp. 1-171); the second is a "Supplemental Record of Appellee" filed by appellee in said Court (pp. 1-46); and the last division contains records of proceedings in the Court of Appeals (opinion etc.) (numbered as pages 3 to 20). Inasmuch as these three divisions are not consecutively page-numbered, we will use the following designations to indicate to which portion of said record reference herein is made: The first division (i.e. the "Record" filed by appellant in the Court of Appeals) will be designated as "R". The "Supplemental Record of Appellee" will be designated as "SR", and the third division of the record (i.e. the Clerk's record of the proceedings in the Court of Appeals) will be designated as "C.R."

MATTER INVOLVED.

The U. S. District Court, in libel proceedings under the Federal Food, Drug and Cosmetic Act, condemned as misbranded and "worthless" various interstate shipments of this Colusa Oil previously seized by the Food & Drug Department.[2]

At the trial below (without a jury) *many witnesses,* including many medical doctors of long practice and many lay "skin sufferers" from various walks of life (business executives, war veterans, retired artisans, housewives, etc.) testified in a clear-cut and detailed *factual* manner *as to the great good accomplished by their use of Colusa Oil in the treatment of these horrible skin diseases.* Most of these skin sufferers, before their use of Colusa Oil, had treated in vain with dermatologists and other medical experts, including the Mayo Institute. Colusa Oil gave them substantial relief, and, in many cases, completely cured their repulsive skin scourges. Not one line of this mass of factual evidence was refuted or impeached in any manner whatever. So cogent was petitioner's medical testimony below that the Court of Appeals, in its summation of the testimony of these many medical doctors, stated:

> "* * * Their testimony was that they had found Colusa Natural Oil and Colusa Natural Oil capsules

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[2]The Food & Drug Administration instituted in 1947 a widespread series of "multiple seizures" of this drug at various points throughout the United States. Condemnation proceedings (libels) were filed in various U. S. District Courts (Colorado, Wisconsin, Iowa, etc.) to condemn various shipments of this drug thus seized. Petitioner intervened in these various libel proceedings and claimed ownership of the seized drugs. Thereafter and by stipulation of the parties these various libel proceedings were tried as consolidated causes, in the United States District Court, at Waterloo, Iowa, in November, 1947.

> both efficacious in the treatment of the four skin diseases named in the quoted labels; that it had in many cases effected permanent cures and had resulted in great relief in all cases." (C.R. 14.)

Notwithstanding these indisputable facts, the trial Court completely disregarded this wealth of uncontradicted evidence and, basing its findings and judgment solely on the "opinion" testimony of a few "experts" (whose testimony constituted the *entire* case of the government) branded this oil as "worthless".

Furthermore, the trial Court concluded (as an indispensable predicate for its decision) that the Colusa label *(which contained no statement or representation that this oil would prove efficacious in the treatment of any of these diseases)* should be construed as representing that this oil *would cure or alleviate all types, phases and stages of these skin diseases.*

These various libels charged that these shipments of Colusa Oil were misbranded in that the statements on the Colusa label:

> "* * * are false and misleading in that such statements represent and suggest that the articles when taken individually or in combination are effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot and open sores, whereas the articles when taken as directed are not effective for such purposes." (R. 3.)[3]

All of these consolidated libel proceedings were based *solely* on the Colusa *label* which reads as follows:

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[3]The word "articles" refers to "Colusa Oil" (sold in bottle form) and Colusa capsules (in capsule form).

"A natural unrefined petroleum oil intended for use in treatment of Psoriasis, Eczema, Athlete's Foot and Leg Ulcers. Directions: apply to affected parts and rub it in thoroughly morning and night. For open sores saturate cotton pad with oil and bind on by gauze. Change to fresh dressing morning and night. For tender skin oil can be diluted 50% with olive oil. Continue treatment until skin is smooth and comfortable. We suggest in treatment of Psoriasis, Eczema and Leg Ulcers using Colusa Natural Oil externally as above directed and Colusa Natural Oil Capsules internally as directed on bottle containing Colusa Natural Oil capsules."

The label on the Colusa Oil Capsules is substantially the same. (R. 21.)

QUESTIONS PRESENTED.

(1) Can a citizen's property be destroyed and his business ruined, by condemnation proceedings under the Food & Drug Act, solely on the basis of the "opinion" testimony of a few expert witnesses? Or, is it still the supreme law, as previously enunciated by this Honorable Court, that the Food & Drug Act only applies to those cases wherein the record shows by *factual* evidence that "*apart from any question of opinion,* the so-called remedy is absolutely worthless and hence the label demonstrably false"?

(2) What *degree or quantum of proof* is required in such drastic proceedings in order to fulfill the gov-

ernment's burden of proof? Is it necessary for the government to prove its charges of misbranding:

(a) *by a high degree of proof*—that is to say, by "clear and satisfactory evidence going beyond a mere preponderance of the evidence" (as stated by the Court of Appeals for the Third Circuit),

or

(b) by a *"mere preponderance of the evidence"* (as stated by the Fifth Circuit and at least impliedly concurred in by the Court of Appeals in the instant case).

(3) Is the decision of the Court of Appeals herein on the subject of its appellate power and duty, in the face of "conflicting evidence" below, an erroneous, confusing and dangerous precedent; and one which is contrary to prior decisions of this Honorable Court and also of other circuits on this same subject?

(4) Is it the law that a drug label which simply contains a statement that it is recommended for use in certain generic diseases must be construed as a warranty that it will prove efficacious in *all cases and phases* of such diseases, even though the label contains no such statement or representation?

(5) Is it the law that testimony of lay (i.e., non-medical) witnesses as to the suffering (itching, burning, etc.) caused them by skin diseases and as to the prompt relief secured by the use of a given drug, is worthless and worthy of no credence, even

though uncontradicted and unimpeached in any manner whatsoever? Was it not highly prejudicial error for the trial court to completely disregard a mass of such testimony?

REASONS FOR GRANTING THE WRIT.

This case presents important questions of general application concerning the standards and burden of proof in food and drug cases. There has been no recent opinion of this Court and the lower Courts are in conflict as to the appropriate standards of proof. The circuit below adopted a standard of proof at variance with that of the Third Circuit. (*Van Camp Sea Food Co., Inc. v. U. S.*, 82 F. (2d) 365. (Brief, p. 1.)

It also adopted a position concerning what is fact and what is opinion at variance with the opinions of this Court. (*American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94; Brief, p. 4.)

This case is a typical case brought by the Food and Drug Administration involving the effectiveness of a remedy for specified conditions of ailments. The government did not allege that the preparation was harmful but only that it was not effective. The decision of the propriety of the methods of proof and the standards applied by the District Court in this typical case (and approved by the Court of Appeals) presents a question of general application which should be and has not been decided recently by this Court.

The government presented opinion testimony by a few medical doctors that this drug is not effective for the prescribed ailments.[4] These men were voicing opinions as to diseases and symptoms concerning which medical science is admittedly very deficient and for which it presently has no adequate or dependable remedies. Petitioner presented contravening medical opinion testimony by many practicing physicians from various parts of the United States (who had made extensive and successful use of Colusa Oil in their practice) that this drug is effective; and petitioner also presented much factual testimony (of lay and medical witnesses) concerning observed results of the application of this drug in many cases of these skin diseases.[5] Most of these observed cases were severe and difficult cases which had previously failed to respond to so-called standard remedies.

It is important that this Court should itself pass on and decide whether seizures may be justified on the type of record here presented. Many persons engaged in manufacturing and selling remedies for various ailments are and will remain, until this Court acts, in doubt whether remedies offered and sold must be supported by substan-

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[4]On the basic issue of use and efficacy of Colusa Oil in these skin diseases, the government's case below consisted essentially of the testimony of *three* medical doctors (Drs. Rostenberg, R. 35, S. R. 2; Trunnell, R. 48; and Carney, R. 52) giving "opinion" testimony, and telling of a few so-called clinical tests made by them of this oil. The government's *entire* case consisted of *nine* witnesses. The testimony of all but these three witnesses was inconsequential and of no real bearing on said basic issue. (In the Appendix to the accompanying brief will be found a summary review of the testimony of all the government evidence. App. p. i.)

[5]In the Appendix to this Petition will be found illustrative examples of this evidence.

tially unanimous medical opinion or whether divided medical opinion is sufficient to authorize the sale and distribution of their products. A definitive ruling is required on this point and on the collateral question of the degree of proof necessary to establish lack of effectiveness (or if, as the lower Court apparently held, the burden is on the defendant, the degree of proof necessary to establish effectiveness). Once this Court has spoken on these matters, the burden of the lower Courts and of the Food and Drug Administration as well as the manufacturers and distributors of products subject to the Food and Drug Administration will be substantially clarified. We believe the decision of the Court below permits outlawing a drug where its effectiveness involves a mere matter of difference of opinion and not of demonstrable fact; and permits seizure on the basis of a standard of proof which requires a minimum of evidence on behalf of the government. This is in contravention of the opinion of this Court in the *McAnnulty* case and of the Third Circuit in the *Van Camp Sea Food Company* case. Whether such a doctrine shall be adopted presents a question of importance which has not been but should be passed on by this Court.

Furthermore, the legal theory adhered to by the Courts below in interpreting the Colusa label is not only unsound but presents a matter of general importance to the drug industry. Under this construction of labeling, a label on a drug which is recommended for use in treatment of certain generically described diseases (eczema, etc.) must be construed as a warranty that the drug will prove efficacious in *all phases and cases* of such diseases, even though no

such statement or representation as to its efficacy is contained in said label. (Brief, p. 20.)

Also of general importance in food and drug litigation is the unsound decision below that the uncontradicted testimony of lay witnesses as to physical suffering and relief experienced by them is worthy of no credence, even though uncontradicted or unimpeached in any way; a point as to which this Honorable Court has not expressed itself. (Brief, p. 7.)

Accordingly, it is respectfully submitted that to clarify differences of opinion between the Eighth and Third Circuits, and the application of the earlier decisions of this Honorable Court, and to definitely settle the other important general legal points aforementioned, a writ of certiorari should be granted.

DATED: November 3, 1949.

WALTER M. GLEASON,
Attorney for Petitioner.

ARNOLD, FORTAS & PORTER,
Of Counsel.

(Appendix Follows.)

Appendix

SUMMARY REVIEW OF PETITIONER'S EVIDENCE BELOW.

Petitioner's case on the issue of "efficacy" consisted of the testimony of *thirty* witnesses from various parts of the United States; fifteen "lay" witnesses and fifteen medical doctors, most of the latter being practicing physicians of long experience in the medical profession.

These witnesses testified, *in a clear cut and detailed factual manner,* as to the excellent results achieved by the use of Colusa Oil in the treatment of a host of severe cases of these skin diseases. Many of these cases had previously failed to respond to other remedies or extensive prior treatments by medical experts and medical institutions (Mayo Bros., etc.). Furthermore, while petitioners at no time represented that this oil would "cure" these diseases or even materially benefit any particular case thereof, this mass of undisputed evidence clearly shows that *this oil has completely cured many severe cases of these diseases.*

Typical Testimony of "Lay" Witnesses: The testimony of the "lay" witnesses below followed a strikingly similar pattern. Most of them had been afflicted for years with severe cases of these skin diseases, attended by intense physical torment. They had treated with medical doctors and medical institutions (Mayo Bros., etc.) for extensive periods, with little or no success. Finally, in one way or another, they learned of Colusa Oil; tried it; and promptly secured relief and excellent results, including in many instances complete cures of their diseases. Typical of

this "lay" testimony is the case of *Mr. Carl E. Veth* (R. 81), aged 54, secretary-treasurer of the Smith Agricultural Chemical Company, of Columbus, Ohio (a large midwestern company), who told of a miserable skin disease suffered by him for some 18 to 20 years:

> "Shortly after the First World War, I developed running sores on my right limb, a space covering about 4 to 6 square inches about half way between the knee and the ankle. It lasted about 18 to 20 years, it itched more or less all the time with much greater itching during the night. This itching naturally kept me awake a considerable portion of the time. The itching was intense, usually at night. There was very much discharge from it; seemed to be more at night and the hose I wore were a mass of wet matter covering the sores up to the top of the hose." (R. 81.)

He told of his unsuccessful treatments with various medical doctors and specialists:

> "I treated with quite a few medical doctors for the ailment from time to time over the whole period of 18 to 20 years, about six doctors, all in Columbus. Some said they were skin specialists.
>
> Q. What did these doctors do in treating your skin affliction?
>
> A. One used some kind of a liquid and solution; two of them used a salve, and I think three of them used a kind of a powder. I don't know what it was.
>
> Q. Did they cure this aliment?
>
> A. They did not.
>
> Q. Did they give you any substantial relief?
>
> A. None whatever, not even a reduction in the itching." (R. 81-82).

Then Colusa:

"A. I applied it with my fingers the first night and the first night the itching was greatly reduced the early part of the first night and the next morning it had stopped. Shall I carry on from there? I continued to use this Colusa Natural Oil on that skin sore for a total of about ten days with once a day application. Then I didn't need it any more. The sores began drying up within less than a week, and from then on it was just a question of time removing the scales and pus sacks, whatever they were. That took less than a month for the complete cure. At the end of that month period the sore was completely healed and it has never recurred since. I used nothing but this Colusa Natural Oil during that time. During the time of treatment with medical doctors and also in the course of my self-medication with other advertised remedies, I used several different drugs, but there was no relief whatever from the other products and Colusa cured it." (R. 82).

And yet the trial judge held Colusa to be worthless!

This gentleman, whose leg was such an offensive and agonizing affliction for so many years, knows more about the value and efficacy of Colusa Oil than the Government's "experts" will ever know!

Another striking example of Colusa's efficacy is *David E. Rowntree* (R. 83), aged 47, manager of the Genesee-Orleans Vegetable Growers Cooperative Association in New York State, who contracted, in 1926, a horrible skin disease which almost drove him crazy:

"I contracted the disease in 1926. It was on my legs, elbows, back and scrotum and was terrifically

itchy. I couldn't sleep at night and had sleeping pills beside me and eight or nine detective books and I read until four, five or six o'clock in the morning. It had scales on the top and a watery substance would come out, it was very red. At times I had scales ¼ of an inch thick. I was ashamed to go to the golf club and take my clothes off and take a shower. I contracted it in 1926. In 1931, I went to the hospital with a nervous breakdown. I was 31 years old and I went down from 160 pounds to 105 pounds. I had 40 doctors." (R. 84).

"The doctors did not cure my disease. The only relief I had was from x-ray treatments and they had to be careful with those to keep from destroying the skin. The doctors treated me with medicines of various kinds. I tried every prescription they gave me. They had lotions and salves and it just seemed as if it itched more when I put them on and I would go back and they would say to try another one and I did. I tried everything. From 1926 to 1943 I tried maybe 100, maybe 90 or 80 drugs, all different, a very large number, none of them gave me relief, only the x-ray. It would last about two days and I wanted another one and they wouldn't give it to me." (R. 85).

Then Colusa:

"I got wonderful results from the use of Colusa. I put a bottle of it on and I slept for the first time since 1926. It helped my skin. It stopped the itching and gradually the scales disappeared, and I got smooth again, my skin became smooth. Colusa Natural Oil gave me relief, the other remedies didn't relieve me at all and this gave me relief. I still have trouble with that skin disease from time to time. I

still am using Colusa. I use it to take away the itching and the scales. In my case the disease follows a pattern of recurring nerves. When it recurs I get the oil out and start putting it on and keep rubbing, and I get immediate relief. When I use it I am itchy and it bothers me, but nothing like it did before I got Colusa. When it recurs if I use it religiously, use it every night, I get it cleared up in about two or three weeks. I get it cleared up and I have no itching and no scales." (R. 85-86).

And this is the same oil which the trial court condemned as "worthless"!

Another illustrative case is that of *Earl H. Hatrick* (R. 87), 40 years old, a contractor from Litchfield, Minnesota, who described a skin disease suffered by him in World War II, viz.:

"I had it on both feet, my right wrist and on my right ear. I was honorably discharged from the Army on July 11, 1945, and I went back home and my condition, according to the Army, was 30 per cent disability because of this skin affliction." (R. 87).

"When I was discharged from the Army, I was 30 per cent disabled. When I got home from Saline, Kansas, I had to throw my shoes away. I couldn't wear them any more, it was that bad." (R. 90).

"It was scaly, had pus, and I had great difficulty in even wearing a sock. When I put a sock on it would hurt and kind of ooze out and one time I was home on furlough and I had quite a time getting back because I couldn't hardly get my shoe on and the same way with my sock. There was itching but no pain, the itching varied from mild to severe." (R. 88).

His efforts to get relief from medical doctors:

"I treated with doctors about 4½ months and picked up what I myself thought might relieve it, at drug stores. I tried everything I thought might help. Dr. Danielson used something, more or less a tar, coal tar, and he bandaged my foot and I would leave those bandages on from 3 to 5 days at a time and they were as stiff as a board. That was all he ever used, he put it on and bandaged it for me. It gave me relief but didn't cure me, it stopped the itching and took off the scales. I was looking for relief from the itching, was always looking for a complete cure." (R. 88).

One phase of the extreme suffering of this veteran:

"One time at San Antonio in the Army hospital I had both feet skinned completely, with a skinning knife, the skin was completely off—it was raw meat. Yes, they skinned it completely off. It wasn't too pleasant." (R. 88).

Then Colusa:

"I started using Colusa Natural Oil on it in the spring of 1947. I saw an ad in the Minneapolis Journal and procured it through a local druggist up there and I gave it a fair trial. I didn't get any of the capsules, just the oil.

I took it home. I figured it was a little too high in price but I put it on and the first day it performed a miracle, I might say, but it seemed too strong for my skin so I diluted it with olive oil as per directions on the bottle. From then on I had no trouble and I worked every day and on November 3rd I was examined by the Veterans Administration and they said

my case was coming along fine. I applied the Colusa Oil myself to the afflicted parts of my body. It gave me relief. The itching stopped within two or three days and finally it started peeling off and it just gradually kept getting better and better." (R. 88).

"It was effective but it seemed to work too fast. It didn't hurt. My feet were scaly and I was probably so anxious to get it cured that it seemed to work too fast. I began figuring, it removed all of the scales and my feet became red, they were not red before, and my wife said not to use it for a few days and I discontinued it for probably 2½ days and my feet started to clear up and the scales were gone from that day forward and never returned." (R. 90).

This witness is a good example of the effect of depriving skin sufferers of this helpful oil:

"I am not using Colusa Oil on the spot I now have on my right ankle because I don't have any. I couldn't get any more through the druggist up there for some reason. I tried to get it and he said that it was impossible to obtain it, so I let it go. It is the Rexall Drug Store at Litchfield, Minnesota, the druggist's name is Butterwick. If I could get some I sure would use it." (R. 89).

One of the unfortunate victims of the illegal multiple seizures resorted to by the Food & Drug agents in their efforts to prevent the American people from securing Colusa Oil was *Mrs. Bird Langenhagen* (R. 64), of Greene, Iowa. This woman has suffered from a leg ulcer for about 32 years, and has treated with a number of medical doctors (R. 64). About a year and a half previous to the trial at Waterloo (in November, 1947), she purchased

some Colusa Oil at the Rexall Drug Store in Waterloo, and it helped her very much, viz.:

> "It gave me substantial relief from the pain which I had suffered from the sore. Colusa alleviated that pain." (R. 65).
>
> "The Colusa Oil reduces the burning materially. The burning sensation becomes intense if I can't take care of it." (R. 65).

Because of the Food & Drug seizure at the Rexall Drug Store in Waterloo, Iowa, this woman was prevented for a period from obtaining this oil which helped her so much:

> "It was some little time before I could get any more. I saw an advertisement on the bottle and sent to Los Angeles to get it. I received some through the mail. I would say I was out a couple of weeks before I could get it again, approximately. During that time I used something I had had before to keep it from hurting so badly. I suffered pain from this sore while out of Colusa. Then I secured a supply of Colusa Oil and it is helping me." (R. 65).

What a perversion of the true and commendable purposes of the Food & Drug legislation it is to thus prevent, by unlawful multiple seizures, American citizens from obtaining a product which they have tried and tested; *and with which they are fully satisfied!*

Of the many pitiful cases of hideous skin scourges revealed in the testimony below, the most tragic and heartrending of all, was that of *Theresa J. Loughran* (R. 90), a retired teacher of music, aged 69 years. An injury suffered by her in the San Francisco earthquake of 1906 resulted in a severe case of leg ulcers:

"It became inflamed and enlarged and my two legs were three times their natural size and they became putrid. I was like a leper with those two legs, and I had thirty-six years of the best of my life taken out of it from those two affected limbs. They developed into running sores, and they all ran into one sore from the toes to right below the kneecaps on both limbs, there would be from seven to more sores. The stench was abominable. I always had deodorant with me because the stench was terrific. They were big sores and the entire two limbs were sores completely around from the roots of the toes to right below the kneecaps, and when boric acid compresses were removed they were covered with pus and they were positively rotting on me. I never was without pain. I had excruciating pain, terrific pain. I had a few intervals where there was a healing effected, but it was humiliating, and the legs were soft and flabby and it wasn't very long before they would break out again. It deprived me of my sleep, I would catch five minutes now and then. I never took any sleeping potions but whatever the doctor prescribed I took and I guess I was under opiates many times unknown to myself. I was in a very pitiful condition during those 36 years." (R. 91).

"On one occasion I begged Dr. McGettigan to amputate the two legs as I was suffering so intensely." (R. 92).

Her pre-Colusa doctoring:

"I consulted with medical doctors who were tops in the profession, about 7 or 8 of the leading doctors, and many other doctors that I just called in. There was Dr. C. F. Buckley, Dr. C. A. Clipton and Dr. Griffin, and, of course, I had the medical staff of St.

Mary's Hospital at San Francisco. The interns in between the doctors visits, they came in and looked me over and helped me some. I also went to doctors that I didn't know for a visit and their opinions and paid for their prescriptions, which didn't do me a bit of good." (R. 91-92).

Then Colusa:

"The circumstances under which I first heard of Colusa Oil were as follows: On January 26, 1941, I went to bed in a dying condition. I went to bed to die. I was there a whole year, up to December, when I heard a great jubilation throughout the household over the finding of some oil that was doing my grandniece a tremendous amount of good. She had an eczematous condition.

Mr. Levinson. Objected to and move to strike.

The Court. Objection sustained.

She had skin trouble. She used this oil on that skin trouble and it seemed there was an improvement, a great improvement. There was great joy and happiness in the household about it. Since I had spent over $10,000 on this eczema condition between medical doctors, hospitals, nurses, medical specialists and sundries of all drugs and descriptions, I thought $2 more would not be anything, so I asked my nephew if he would take it and bring me a bottle of that oil, and he brought a bottle of Colusa Natural Oil to me. The night he brought it home I applied it, I was kind of skeptical, kind of afraid of it, and it seemed to be rather soothing and I applied it the next morning and the next forenoon and after the third application and when I went to apply it the fourth time I saw that it was very evident that there was a change, there seemed to be a slight scum on it, over the affected area, and I continued on with it and at the

end of three weeks and three days those two legs were perfectly cured and since then I have not had a pain or an ache after 36 years of suffering, or spent another five cent piece on it. I didn't use anything else on my legs from the time I began putting Colusa Natural Oil on them. When I started using Colusa Oil my legs were completely covered with sores, they were putrid at the time and the smell was terrific. I started to use it in the early part of December and on the 5th of January 1942 I was thoroughly cured of it." (R. 92-93).

"There was a burning sensation in connection with this skin trouble, it was like a stilleto driven into the two limbs and the flesh ripped to the bone. That was the feeling I had from the beginning for 8 years before I had any cessation of that. I couldn't call it itching, the pain was too intense to allow any itching or any rubbing or anything. The first night I applied Colusa Oil there was a soothing feeling and at the end of the second night there was considerable less pain and at the end of the third night less, and at the end of the week I hadn't a ray of pain. I was able to sleep without sedatives for the first time in 36 years the whole night through. Recalling those years of suffering affects me very much, it was a very sorrowful experience." (R. 94).

And yet it is judicially decreed that this oil is "worthless"! And that there was no "credible" evidence that this oil has any value!

This unfortunate lady, with her 36 *years* of ghastly Gethsemane, *knows* more about the suffering and agony incident to these skin diseases and what *real relief* therefrom means than all the Government's so-called "ex-

perts". Her testimony alone, we respectfully submit, is worth more than the tenuous "opinions" and fine-spun theories of a dozen "experts" such as those produced by the Government in this case.

The record below is replete with many other similar factual narrations of the great good which has been accomplished by the use of this natural medicinal oil. Not one line of this host of factual testimony was disputed or impeached.

Typical testimony of Intervener's medical witnesses: A brief summary of the testimony of *Dr. C. L. Bonham* (R. 737), of Seattle, Washington, an M.D. of 40 years practice, will illustrate the nature of Intervener's medical testimony. He testified (by deposition) in considerable detail as to his long and successful use of Colusa Oil in the treatment of these skin diseases. This physician has practiced approximately 40 years in the University District of Seattle (University of Washington) and his patients have been largely residents of that district. (R. 147.) He testified that he had had an extensive practice in the field of dermatology. (R. 140.) He has used Colusa Oil for over 25 years, viz.:

> "I first heard of Colusa Oil over 25 years ago and have used it off and on whenever I could get it since that time." (R. 139.)
>
> "I don't know how many patients with eczema I have treated with Colusa Oil; throughout the years, lots of them; about 24 to 30 eczema cases in the past 3 years probably." (R. 141.)

He described in detail many of the cases thus successfully treated by him with this oil. The following are a few:

"There was a woman who was placed in a sanatorium out north because she was given up by some skin specialists. They couldn't do anything for her. They had tried allergy tests, of course, and I was called by the head nurse to see her, she was a pitiable sight. This was five years ago, she was 54 years old. She had an eczema, a weeping eczema and the crusts were so heavy that her lower eyelids were held open and buried. She was covered from the crown of her head to the sole of her feet. It extended from her scalp to her toes practically one unbroken mass. She took Colusa Oil. I had the nurse rub her from head to foot with it twice a day and bathe her. In seven weeks she left the hospital. The last I saw of her she was cooking in a lumber camp, that was three years ago. She was completely cured of the eczema. I gave her no other treatment but the Colusa Natural Oil. There was a case where all the allergy tests had been performed before I had the case." (R. 142.)

"Another case, a man 67 years old with weeping eczema on both hands. I prescribed Colusa Oil and in only 45 days his hands were perfectly restored and normal." (R. 138.)

"Another case, a woman with psoriasis, 55 years old; a psoriasis of the circinate type covering both breasts, abdomen, both hips, thighs and calves and back of the neck, reaching up into the hair for about a distance of two inches. I prescribed Colusa Oil. She was cured entirely, leaving no trace, no scar, no evidence of psoriasis in 3 to 4½ months." (R. 139.)

"I recall another case I treated about 3 years ago, a male about 70 years old, he had eczema on

his hands, medium, the squamous type. I found nothing from the allergy tests. I prescribed Colusa Oil for him, he bought his own. He was cured in approximately 30 days, maybe a few days more or less, I did not actually see him use it, only his say so in telling me 'That oil was great stuff.' I have seen him since, the eczema has not returned; emphatically no." (R. 142.)

Dr. Bonham was emphatic in his praise of this oil:

"I have just merely used this Colusa Oil generally and got very good results with it. I think it is efficacious in the treatment of all types of eczema and all stages of those types, I am sure it is efficacious. Whether you gain a cure in every case, I would not say that you will, but efficacious, yes. Efficacious, of course, means producing an improvement." (R. 141.)

"I haven't treated a great many people for leg ulcers with Colusa Oil but I have had considerable success with it." (R. 142.)

"I have seen Colusa Oil effect a complete remedy where other remedies have failed completely. I have certainly seen it effect an improvement where no other remedy had, where another remedy had been used and failed to effect a cure or improvement." (R. 146.)

And there is no "credible" evidence that this oil has any value!

This witness also emphasized another important aspect, the "economic phase" of the matter of treating these difficult skin ailments; a phase of great importance, of course, to the ordinary American citizen, viz.:

"I prescribed Colusa Oil because I knew it to be efficacious. I thought it would work better than some other remedies available to me. It might possibly work better because of the ease by which it could be applied by the patient. It might have saved the patient the need of having to come to a clinic for application of the particular remedy, they could ill afford it. *I bore in mind the relative cost of those more elaborate remedies such as x-ray and radium as opposed to a practical remedy such as Colusa Natural Oil.*" (R. 146.)

The importance of this "economic phase" to the American people was likewise brought out in the testimony of *Mrs. Bertha E. Cohn* (R. 115):

"The skin specialist in St. Louis gave me some sort of a salve too, I went to him only once, it was during the depression and *I couldn't afford to go to skin specialists.*" (R. 117).

Another medical doctor who testified for Colusa was *Dr. P. D. Stout* (R. 98) of Bristol, Virginia, an M. D. and dermatologist of 25 years practice, a member of the staff of King Mountain Memorial Hospital in Bristol, Virginia, and a member of the American Medical Association. His testimony was by deposition. He testified that he had "made a concentrated study of skin diseases in connection with my practice for approximately 20 years." (R. 99). This trained and experienced dermatologist paid emphatic tribute to the efficacy of Colusa Oil, viz.:

"I regard Colusa Natural Oil to be efficacious in treament of Chronic Eczema and various irritations of the skin, athletic's infection on hands and feet; dry

scaly skins practically always improve under Colusa Natural Oil locally applied and capsules taken by mouth, particularly Seborahoeic Dermatitis. *The cases of psoriasis I have treated with Colusa Oil and Capsules have responded more readily than any other remedies employed to date.* One case in question shows that after psoriasis for a period of 20 years it was practically well after a few months on Colusa Oil and Capsules." (R. 98-99).

"Some of the patients I have treated with Colusa Natural Oil and capsules had previously failed to respond to other forms of treatment, did respond to Colusa Oil and capsules fairly readily." (R. 99).

He related much detail as to some of the cases treated by him with Colusa Oil and the fine results achieved (R. 99-102), for example:

"I used Colusa Oil locally and personally with good results on Mrs. C., 1935 to 1936. It was the deepest leg ulcer of its type ever encountered. She had a swollen, fleshy leg, the veins were not accessible for an injection with sclerosing substances, so all of her treatment was purely local, rest, etc. A very severe case. A very severe case, looked like the circulation to the foot might be cut off." (R. 102).

and:

"I have used Colusa Oil in the treatment of athlete's foot, one case Mr. S., Bristol, Va., age 22, male, about 1940, treated daily. The skin on practically all of his toes on both feet peeled almost to the bleeding point, the entire horny layer being involved, excessive drainage of serum and pus with itching pain. A very severe case. About 1940, prescribed oil locally. I also used ultra voilet in my office. Patient cleared

up after 12 to 15 days so that he could resume his work and get around. I have frequently treated cases of athlete's foot subsequent to that time." (R. 102).

Moreover, the testimony of both the government doctors and petitioner's medical experts concurs in the view that one of the most important phases of the treatment of these baffling skin diseases is the elimination (or lessening) of the intense itching, burning and other severe physical suffering incident to these diseases.

As the principal witness for the government below (Dr. Rostenberg) admitted on cross-examination:

"Alleviation of such physical discomfort is part of the treatment, an important part." (R. 41.)

The mass of undisputed evidence below proves, as clearly as any fact could ever be proved, that Colusa Oil is very effective in alleviating and eliminating these conditions. Typical of the potent and poignant proof below on this phase are the following excerpts from the record:

"It itched so that I would have to scratch it until it bled . . . It gave me a burning sensation and it itched so bad that I couldn't sleep at nights . . . It (Colusa) stopped that awful itching and burning and cleared up my skin . . . It cleared up right away." (Ralph E. Patton, R. 77.)

"Many a night I was forced to get up and couldn't sleep at all, or stay in bed because of the itching . . . It (Colusa) helped me. I began getting relief from it within the first week; it eased the itching sensation very much. I was able to sleep better. It continued to improve until it seemed to be healed." (Frank P. Walker, R. 64.)

"My skin affliction was accompanied by considerable itching, I didn't sleep hardly any at night because it was so very bad . . . Colusa Oil gave me more relief than any of these other medicines and I base that on my own actual use of the oil, my own feelings." (Mrs. Albert Farley, R. 79.)

"It itched and I would scratch it at times until my skin would bleed; it burned too. It affected my work and my sleep . . . The Colusa Oil stopped the itching and burning and my skin became normal like it should be, smooth and comfortable." (Clara McClunney, R. 97.)

etc. etc. etc.

Furthermore, intervener's evidence showed that this Colusa Oil is a rare and unique oil, having characteristics closely resembling ichthyol, a precious medicinal product distilled from crude oil shales and crude tars found in Austria. Ichthyol is one of the medical profession's most valuable therapeutic agents in the treatment of these skin diseases (as well as many other diseases).

(Brief p. XXVI.)

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In the Supreme Court
OF THE
United States

OCTOBER TERM, 1949

No. 458

COLUSA REMEDY COMPANY, Intervener,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI to the United States Court of Appeals for the Eighth Circuit.

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In the Supreme Court
OF THE
United States

OCTOBER TERM, 1949

No.

COLUSA REMEDY COMPANY, Intervener,
Petitioner,
vs.
UNITED STATES OF AMERICA,
Respondent.

BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI to the United States Court of Appeals for the Eighth Circuit.

I. THE DECISION OF THE COURT OF APPEALS IS IN CONFLICT WITH A DECISION OF THE THIRD CIRCUIT AS TO THE DEGREE OF PROOF REQUIRED.

There is a direct conflict in the decisions of various circuits on the important subject of the *degree of proof* required in these condemnation proceedings under the Food & Drug Act.

In the case of *Van Camp Sea Food Co., Inc. v. U.S.* (CCA-3) 82 F. (2d) 365, (a Food & Drug case involving allegedly adulterated food), the then Circuit Court of Appeals (Third Circuit) laid down the salutary rule that in such cases it is required that there be:

> "• • • a higher degree of proof than a mere preponderance, a mere balance in favor of the Government . . . It is necessary, in a case like this, that the Government should establish, by clear and satisfactory evidence, that its case has been made out." (82 F. (2d) at 366.)

That Court (in the face of evidence far stronger than the "evidence" of the government in our case) reversed the judgment of condemnation entered below.

However, the government contends in our case (and apparently the Court of Appeals agreed with this contention) that *a mere preponderance of the evidence* is all that is necessary. A decision of the Fifth Circuit (*C. C. Co. v. U.S.*, 147 F. (2d) 820) appears to support this "mere preponderance" rule. The Court in that case first adhered to the rule in the *Van Camp Sea Food* case, but later, on rehearing, reversed itself and held that a "mere preponderance" of the evidence is all that is required.

It is respectfully submitted that this conflict in the several circuits on this very important subject should be resolved by this Honorable Court. It is further submitted that the view of the Third Circuit is the only sound and salutary rule. The destruction of property and the ruin of a citizen's business, by these drastic condemnation proceedings, are such serious and drastic steps that *they should only be sanctioned when a very clear*

showing is made to justify such action. It is no answer to this to state that the Food & Drug statute is a beneficent statute designed to protect the public and should be "liberally construed", and that, therefore, no more than a "mere preponderance" of the evidence should be required in these cases. All criminal legislation is designed to protect the public, *and most of it in far more important and direct ways than this Food & Drug legislation.* Yet it has long been a bedrock principle of our jurisprudence that such legislation must be strictly construed in favor of the accused and that the proof of guilt *must be beyond a reasonable doubt.*

United States v. Resnick, 299 U.S. 207, 81 L. Ed. 127;

United States v. Wiltberger, 5 Wheat. 76, 5 L. Ed. 37;

Fasulo v. United States, 272 U.S. 620, 299 U.S. 207, 81 L. Ed. 127;

50 *Am. Jur.* 430, Sec. 407.

There is no sound reason why the government, in these drastic condemnation cases, should not be held *to a high degree of proof,* as was required by the Third Circuit in the *Van Camp Sea Food* case.

If such a rule were to be applied in the instant case, there could be, we respectfully submit, absolutely no doubt as to the utter inadequacy of the government's "proof" below.

II. THE DECISION OF THE EIGHTH CIRCUIT IS IN CONFLICT WITH DECISIONS OF THIS HONORABLE COURT AS TO WHAT IS OPINION AND WHAT IS FACTUAL EVIDENCE IN FOOD AND DRUG CASES; AND AS TO THE MINIMUM STANDARDS OF PROOF REQUIRED OF THE GOVERNMENT IN SUCH CASES.

This Honorable Court has stated in prior decisions that the Food & Drug legislation must be interpreted as not applying to a case wherein nothing more is involved than mere differences of opinion between experts, and where:

> "• • • the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact." (*American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 23 S.Ct. 33, 47 L.Ed. 90.)
>
> *U.S. v. Johnson*, 221 U.S. 488, 31 S.Ct. 627, 55 L.Ed. 823;
>
> *Seven Cases v. U.S.*, 239 U.S. 510, 36 S.Ct. 190, 60 L.Ed. 411.

The facts as to the history and development of the Food & Drug legislation and the limitations thereon are well stated in *U. S. v. 7 Jugs etc.* (D.C.-Minn.), 53 F. Supp. 746, as follows:

> "Plainly, therefore, the subject of regulation in the 1938 Act, as in its predecessors, is matter of fact, not matter of opinion. See House Committee Report No. 2139, 75th Congress, 3d Session. Except as affected by Section 201(n) and the regulations issued thereunder, it is clear that food and drug legislation was intended to apply only to false or misleading expressions of fact. It seems manifest that the question of whether a remedy is effective is always a question of fact. A remedy cannot be both effective and in-

effective under identical circumstances. The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be adjudged false or misleading within the meaning of Section 502(a). *Necessarily, therefore, whether in a given case the question of effectiveness is one of opinion or fact depends entirely upon the evidence which is introduced.*[1]

Under the law as it now exists, before a court is warranted in submitting the false or misleading qualities of an assertion of effectiveness to a jury to decide, it must be satisfied that something more is involved than mere differences of opinion between schools or practitioners. As stated by Justice Hughes in his dissent in the Johnson case: 'I entirely agree that in any case brought under the act for misbranding—by a false or misleading statement as to curative properties of an article—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. *Conviction would stand only where it had been shown that, apart from any question of opinion, the so-called remedy was absolutely worthless, and hence the label demonstrably false.*' 221 U.S. 507, 31 S. Ct. 631, 55 L. Ed. 823. If the evidence is such that it appears that the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. American School of Magnetic Healing v. McAnnulty, supra; see L. B. Silver Co. v. Federal Trade Commission, 6 Cir., 1923, 289 F. 985; cf. Bruce v. United States, 8 Cir., 1912, 202 F. 98. But where the evidence indicates that there is a

[1]All emphasis in this brief, either by italics or otherwise, is petitioner's unless otherwise noted.

standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. *What the evidence shows in a given case is a question of law for the court to decide.*" (53 Fed. Supp. at 758.)

"Although the court in the McAnnulty case had said that assertions of effectiveness were always matters of opinion because 'There is no exact standard of absolute truth by which to prove the assertion false and a fraud * * * (since) * * * the claim * * * cannot be the subject of proof as of an ordinary fact,' 187 U.S. 104, 23 S. Ct. 37, 47 L. Ed. 90, the court now states that there is a category of assertions which fall outside the field of opinion and into the field of fact. 'Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners * * * Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion, but constitute absolute falsehoods.' Seven Cases v. United States, 239 U.S. page 517, 36 S. Ct. page 193, 60 L. Ed. 411, L.R.A. 1916D, 164." (53 Fed. Supp. at 757.)

It is respectfully submitted that the government's "evidence" in the instant case, consisting as it does of the "opinions" of a few expert witnesses, testifying concerning diseases as to which medical science admittedly is greatly deficient and inadequate, does not even begin to comply with or fulfill the salutary standards of proof laid down in the aforementioned prior decisions of this Honorable Court. The pattern of proof sanctioned by the Courts below is a complete departure from these sound principles previously enunciated by this Honorable Court,

and this harmful precedent should be repudiated and eliminated. *Certainly such a dangerous pattern of proof should not be sanctioned by any Court.* Before such destruction of property is judicially permitted, there should be (as this Honorable Court has so wisely previously required) a clear demonstration, by *factual* evidence, of the public necessity therefor.

And, in this connection, may we not briefly stress one other significant aspect of this case and of the proof below? The Food & Drug Department had ample opportunity (i.e., years) to prepare its case against Colusa Oil. The government had at its command a multitude of hospitals, laboratories, clinics and other first class medical facilities wherein it could have made *real tests* of Colusa Oil in hundreds and thousands of cases *(under fully controlled testing conditions).* Why, instead of such a scientific test, did it have to resort to this "opinion" evidence which constituted its entire case herein! And why, in view of the widespread national distribution of this Colusa Oil through the years, did the Food & Drug Department fail to call a single dissatisfied Colusa user to the witness stand in this case?

III. THE COMPLETE DISREGARD BY THE TRIAL COURT OF THE LAY TESTIMONY WAS ERRONEOUS AND HIGHLY PREJUDICIAL AND THE APPROVAL OF THIS ACTION BY THE COURT OF APPEALS CREATES AN UNSOUND AND HARMFUL PRECEDENT.

The trial Court completely disregarded a mass of clear-cut and unimpeached factual testimony of the many

Colusa "lay users" as to the excellent results achieved in treating their skin diseases with Colusa Oil. This "lay" testimony consisted of detailed and cogent factual evidence as to what these people *had seen and felt* in their use of Colusa Oil in the treatment of their horrible skin diseases.

Yet the trial judge swept it all aside! He made it manifest early in intervener's case that he considered this testimony of little or no importance. In the course of the testimony of petitioner's very first witness (Frank Walker, R. 59) the trial judge made reference to:

> "* * * people who tied toads around their necks and believed they had a splendid cure; and then you have the matter of baths and that certain spring waters have curative properties . . ." (R. 63.)

and warned intervener's counsel that:

> "We will limit the number of lay witnesses we will hear on this line of testimony." (R. 63.)

In his findings herein, the trial judge made even more patent his complete disdain for and disregard of this mass of forceful factual evidence. Notwithstanding that this unimpeached testimony of these many Colusa users clearly proved, in a detailed way, the great good accomplished by the use of Colusa Oil, the trial judge found, in effect, that none of this evidence was worthy of credence; and that this product was "worthless." (Finding 19, R. 13.)

This basic view of the lower Court was and is, we respectfully submit, patently erroneous. *These skin sufferers were and are very valuable and competent judges and witnesses as to:*

(a) *The extent of the misery, suffering, agony, etc. caused to them by these obnoxious skin diseases,*

and

(b) *The location, severity and all other relevant facts observed by them as to the extent and course of their said skin diseases,*

and

(c) *The extent of the relief, if any, accomplished by the use of a particular drug; and the results and effects noted by them from the use of such drug.*

The trial judge was apparently of the belief that in a case such as this the only testimony of any value is that of medical experts. Under the circumstances of this case, this view was not only erroneous but highly prejudicial.

AUTHORITIES RE COMPETENCY AND WORTH OF SUCH "LAY" TESTIMONY.

The settled law as to the competency of such testimony is summed up in Corpus Juris as follows:

> "A lay witness may not diagnose disease as an expert but he may testify as to facts within his own knowledge. A witness has been permitted to testify as to his own health or physical condition, his statements being in some cases regarded as a collective statement of fact; and in this connection he may state his suffering, or nervous condition, injury, prior condition, or recovery * * *" (32 *C. J.*, p. 108, Sec. 467.)

The following are a few of the many cases exemplifying this settled legal principle, viz.:

Townsend v. Keith, 34 Cal. App. 564, 168 P. 402;

Equitable Life Ass. Soc. v. Davis (1936), 265 Ky. 259, 96 S.W. (2d) 689;

St. Louis-S.F. Ry. Co. v. Clark, 104 Okl. 24, 229 Pac. 779;

Asch v. Washburn Lignite Coal Co., 48 N.D. 734, 186 N.W. 757.

In the *Equitable Life Ass.* case, supra, the Court emphasized, with respect to the testimony of a lay witness as to his own ailments, that:

> "Certainly he was in a better position than any other person, including physicians who testified, to tell how his alleged injuries affected him. These were matters clearly within his knowledge." (96 S. W. (2d) 689, 690.)

The California court, in *Townsend v. Keith,* supra, in passing upon the propriety of the question: "Since the accident, have you had the use of the injured leg as you had before?" emphasized this same common sense rule that:

> "Assuming that the question called for the opinion of the witness, nevertheless it called for evidence of a material fact, *which came from the best source of knowledge.*" (Italics ours.) (168 Pac. 402 at 403.)

In the *St. Louis-S.F. Ry.* case, supra, it was claimed in the Supreme Court that the court below had erred in permitting a layman to testify as to his treatment at a hospital and the results achieved in relieving his suffering, etc. The Oklahoma Supreme Court quickly disposed of such contention:

> "* * * the rule in those cases goes to the question of diagnosis and could not apply to relief from pain and torture of nerves and the state of comfort and enjoyment after suffering."

In the *Asch* case, supra, the same theme was well expressed:

"The injured person is a competent witness to testify to his feelings, pains and symptoms, as well as to all the characteristics of the injury, internal or external, so far as the same were perceptible to the senses, and do not require the exercise of scientific skill and knowledge; *and indeed it has been held that he is better qualified to testify to such matters than anyone else.*" (186 N.W. 757, 765.)

The highly prejudicial nature of the error of the trial Court in completely disregarding this "lay" testimony becomes even more apparent when it is realized that the Government's entire case collapses *if the proof shows that Colusa Oil "alleviates" these skin diseases.* In other words, it is conceded by the Government (as it must be) that the Colusa labeling makes no claim that it will "cure" these diseases. In fact, the Colusa label does not even state that the oil will prove efficacious in treating any particular case or phase of these diseases.

Under these circumstances, it is indisputable that if Colusa is useful in "alleviating" or "palliating" *in any manner* these skin diseases, the Government's case collapses. Can there be any doubt that Colusa Oil *does* alleviate these skin afflictions:

"It stopped that awful itching and burning * * *". (Patton, R. 77.)

"The Colusa Oil reduces the burning materially * * *." (Langenhagen, R. 65.)

"It stopped the itching * * * I got wonderful results from Colusa * * *." (Rowntree, R. 83.)

"The Colusa stopped the itching and burning * * *." (McClunney, R. 97.)

etc., etc., etc.

Of course, the evidence goes far beyond proving merely that Colusa Oil is an efficacious remedy in thus *alleviating and palliating* these skin diseases. As the record plainly shows, Colusa Oil has completely cleared up and cured many of the cases testified to in the Court below. However, if it did no more than reduce or otherwise alleviate the physical suffering incident to these diseases, it would still be a welcome and badly needed remedy. This becomes particularly apparent when it is realized that the medical profession (including its specialists) was unable to even "relieve" or "palliate" most of the cases testified to in the lower Court:

> "I went to family doctors, three or four. They prescribed an ointment. It had no effect on my skin trouble that I could see. I tried these medical treatments with doctors for several months and I got disgusted. They didn't help me and it was just a waste of money." (McClunney, R. 97.)

> "When I was doctoring with these doctors and using the things they gave me, I didn't see any improvement in these sores on my ankle. When I applied Colusa Oil there was a change, I liked it very much • • • Colusa Oil gave me good results right away • • •." (Goranson, R. 109, 110.)

> "Dr. Stann • • • didn't do any good, no results • • • Neither doctor alleviated my itch, no good at all • • • I treated with Dr. Aurner (a skin specialist) twelve times—he tried a number of different methods • • • he didn't help me • • • I treated with Dr. Tice (Chicago) • • • He told me he couldn't help me • • • I received no help from any of these doctors or medical institutions." *Re Colusa Oil:* "It helped me. I began getting relief from it within the first week;

it eased the itching sensation very much; I was able to sleep better, etc." (Walker, R. 62, 63.)

"I went to skin specialists at Cedar Rapids, Dr. Kurt, for about 3 or 4 weeks; and they finally told me they couldn't do anything for me * * * My skin condition did not improve with these treatments. It was getting worse all the time * * * I was at the Rochester clinic for two weeks, they were treating me * * * My skin condition was not alleviated at all, it kept getting worse all the while I was there * * *." (Bergeson, R. 111-112.)

"I used about 8 or 10 remedies prescribed by Dr. Theilen. None of them gave me any essential relief * * * I did not experience any particular relief from the use of the treatment and the other materials I used." (Kistner, R. 113, 114.)

etc., etc., etc.

It must be remembered that we are dealing in this case with miserable skin scourges apparent on the surface of the human body. Yes, all too palpable! We are not dealing with hidden or recondite internal diseases of the kind which only an expert might be able to detect, locate or treat.

Is it not strange that, under these unquestionable circumstances, the trial judge below should consider as valueless the testimony of these skin sufferers who really are the most competent and valuable of all witnesses as to the facts concerning their own skin diseases, including the relief afforded them from the itching, burning and other suffering incident thereto. Common sense dictates that such a skin sufferer is normally the best judge as to the extent of the *relief and alleviation afforded to him from such suffering by the use of a particular drug.*

The complete disregard by the trial Court of this lay testimony was, we respectfully submit, clearly erroneous and highly prejudicial.

Incidentally the Courts have had occasion to emphasize that a "remedy", to be valuable and justifiable, need not be a cure:

> "But the real definition found in that dictionary is the following: 'Remedy: That which relieves or cures a disease.' The Standard Dictionary gives the following definition: 'Remedy: That which is used in any way for the cure or relief of bodily disease; a medicine; also remedial treatment.' It cannot therefore in this criminal action be concluded that, when the defendant used the word 'remedy' it used it as synonymous with 'cure', nor can it be concluded that the word would be understood by the public to mean 'cure.'" (*U. S. v. Natura Company,* 250 Fed. 925.)

> "The testimony of the experts shows that a therapeutic or curative agent is something which alleviates or tends to cure a disease, and that, except in a few instances, there is no medicine which, of itself, is an absolute cure for disease." (*U. S. v. 23 Bottles, etc.,* 44 F. (2d) 831.)

IV. THE DECISION OF THE COURT OF APPEALS CONSTITUTES AN UNSOUND AND CONFUSING PRECEDENT ON THE SUBJECT OF THE APPELLATE POWER AND DUTY REGARDING FINDINGS BELOW BASED ON "CONFLICTING EVIDENCE". SAID DECISION IS CONTRARY TO DECISIONS OF THIS HONORABLE COURT.

THE LAW AS TO POWER AND DUTY OF A COURT OF APPEALS TO REVERSE FINDINGS OF TRIAL COURT.

It is well settled that:

> "A finding of fact is clearly erroneous if it is against the clear weight of the evidence. It does not

suffice that it be supported by evidence." (*Fleming v. Palmer,* (CCA 1) 123 F. (2d) 749, at 751.)

"The findings of fact of the court below to the extent that they are unsupported by substantial evidence, or are clearly against the weight of the evidence, or were induced by an erroneous view of the law, are not binding upon this Court." (*Aetna Life Ins. Co. v. Kepler,* (CCA 8), 116 F. (2d) 1, 5.)

The United States Supreme Court has clearly defined this appellate function and power under Rule 52(a) of the Rules of Civil Procedure in the recent case of *U.S. v. U.S. Gypsum Co.* (1948), 333 U.S. 364, as follows:

"Insofar as this finding and others to which we shall refer are inferences drawn from documents or undisputed facts, heretofore described or set out, Rule 52(a) of the Rules of Civil Procedure is applicable. That rule prescribes that findings of fact in actions tried without a jury 'shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of witnesses.' It was intended, in all actions tried upon the facts without a jury, to make applicable the then prevailing equity practice. Since judicial review of findings of trial courts does not have the statutory or constitutional limitations of findings by administrative agencies or by a jury, this Court may reverse findings of fact by a trial court where 'clearly erroneous.' The practice in equity prior to the present Rules of Civil Procedure was that the findings of the trial Court, when dependent upon oral testimony where the candor and credibility of the witnesses would best be judged, had great weight with the appellate court. The findings were never conclusive, however. *A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and*

> *firm conviction that a mistake has been committed* • • • Despite the opportunity of the trial court to appraise the credibility of the witnesses, we cannot under the circumstances of this case rule otherwise than that Finding 118 is clearly erroneous.'" (333 U.S. at 394-395.)

The aforementioned authorities show that a federal court of appeals has the power and duty to set aside the findings and judgment of a district court in all cases wherein it appears that the findings are contrary to the weight of the evidence. This is so even though to some degree this may involve the consideration of matters as to which the evidence below is in sharp conflict, and even though "credibility of witnesses" may to some extent be involved.

The decision and reasoning of the Court of Appeals in the instant case departs from this settled principle and constitutes an unsound and harmful precedent on this important subject. Notwithstanding that the entire case of the government consisted of "expert" (i.e., opinion) testimony from a few witnesses and that, on the other hand, petitioner's evidence below consisted of a wealth of *factual* proof as to the efficacy of this oil, the Court of Appeals herein concluded that "the evidence on this issue is conflicting" and stressed the matter of the "opportunity of the trial Court to judge the credibility of the witnesses," and for these reasons decided that the lower Court's finding of "worthlessness" is not "clearly erroneous." (C.R. 16-17.)

This reasoning of the Court of Appeals is, we respectfully submit with all due deference, clearly erroneous in several important respects:

Firstly, it makes no attempt to determine where *the weight of the evidence lies.* The government admittedly had the burden of proving the "lack of efficacy" of this oil; either by *"a preponderance of the evidence"* (if the Fifth Circuit states the rule correctly) or by *"clear and satisfactory evidence going beyond a mere preponderance"* (if the rule enunciated by the Third Circuit is correct law). It is unquestionable that the Court of Appeals should have reversed the judgment below if these findings were deemed to be against the "weight of the evidence." The Court of Appeals failed to determine or pass upon this important phase.

Secondly, the heavy reliance by the Court of Appeals upon the element of the trial Court's opportunity to judge "the credibility of the witnesses" is unjustified and erroneous under the circumstances of this case. There was no "conflict in the evidence" below in the sense that the determination of "credibility of witnesses" was an important factor. The simple truth is that *not one fact testified to by the many witnesses for petitioner* (i.e., the use of this oil in the multitude of cases testified to; the seriousness of these cases; the prior unsuccessful treatments with medical experts; the excellent results observed from the use of Colusa Oil, etc., etc.) *was in any manner disputed or contradicted by the government. This evidence stands wholly undisputed.*

Therefore, we have a situation where the record below indisputably shows *as a factual matter* that this oil *has been used and has produced excellent results in the treatment of many difficult cases of these skin diseases.* Opposed to this uncontradicted *factual* proof is the testimony of a few medical experts for the government who

gave "opinion" evidence and also told of their allegedly unsuccessful use of the oil in a few so-called clinical cases. An Appellate Court can just as easily determine, from such a record, where the weight or preponderance of the evidence lies; and should do so.

We do not have in this case the orthodox situation, which gave rise to the rule as to "credibility of witnesses," in which, for example, one or more witnesses testify that they saw or heard a certain thing, and one or more witnesses testify to the contrary. In such a situation the matter of determining the "credibility of the witnesses" is, of course, an important phase; and one that necessarily is primarily a function of the trial Court. Herein we have no such situation. Furthermore, not only is there no such element in the instant case, but almost all of the medical testimony offered by petitioner was by deposition and in such a situation, the Court of Appeals is in as good a position to weigh and appraise it as the trial Court.

AUTHORITIES ON FUNCTION OF APPELLATE COURT WHERE THERE IS NO CONTRADICTION BETWEEN WITNESSES BELOW ON FACTUAL MATTERS.

It has been repeatedly recognized by various federal Courts that the "credibility rule" vesting large discretion in the trial Court has no real force or application to the situations where there is no conflict between the witnesses below on factual matters. For example, in the case of *British American Assur. etc. Co. v. Bowen*, 134 F. (2d) 256, the Court states (at page 260):

> "But here, the only evidence offered on the issue of whether Bowen set the house on fire or procured it to be set on fire was the written evidence adduced

in the state court action. Parenthetically, it may be observed that the jury there found against Bowen. Hence, the ordinary rule that an appellate court will generally accept the finding of the trial court upon a controverted issue of fact, where the trial court saw the witnesses and observed their demeanor while testifying, is without application. On the contrary, this court is equally capable of examining the evidence and drawing conclusions from it and is under the duty of doing so."

To substantially the same effect are:

Grove Laboratories v. Brewer, 1-Cir., 103 F. (2d) 175;

Nashua Mfg. Co. v. Berenzweig, 7-Cir., 39 F. (2d) 896;

U. S. v. Corporation etc., 8-Cir., 101 F. (2d) 156;

Kaeser & Blair v. Merchants Assn., 6-Cir., 64 F. (2d) 575.

This Honorable Court has had occasion to speak on various occasions of the limitations upon this "credibility rule":

"We recognize the general rule, of course, as stated by both courts below, that the question of the credibility of witnesses is one for the jury alone; but this does not mean that the jury is at liberty, under the guise of passing upon the credibility of a witness, to disregard his testimony, when from no reasonable point of view is it open to doubt." (*Chesapeake & Ohio R.R. Co. v. Martin,* 283 U. S. 214, 51 S.Ct. 453, 75 L.Ed. 983.)

"And, certainly, in the light of these conditions, no verdict based upon a statement so unbelievable reasonably could be sustained as against the positive testimony to the contrary of unimpeached witnesses, all in

a position to see, as this witness was not, the precise relation of the cars one to the other." (*Penn R. Co. v. Chamberlain*, 288 U. S. 333, 53 S.Ct. 391, 77 L.Ed. 819.)

Other pertinent expressions:

"The credibility of Mrs. Quinan was not questioned. Her testimony was not impeached or contradicted. It cannot be disregarded. (*Chesapeake & Ohio R.R. Co. v. Martin*, 283 U. S. 209, 216, 217, 51 S.Ct. 453, 75 L.Ed. 983." (*San Francisco Assn. etc. v. Industrial Aid etc.*, 8-Cir., 152 F. (2d) 532.)

"Appellant concedes that in the federal court, and in many of the state courts, the general rule is that the uncontradicted testimony of a witness not incredible in itself, nor impeached, nor discredited in any way, to plain and simple facts capable of contradiction ordinarily, must be accepted as true by the jury. (Citing authorities.)" (*Gibson v. Southern Pac. Co.*, 5-Cir., 67 F. (2d) 758, 762.)

APPLICATION OF THESE PRINCIPLES TO THE FINDINGS HEREIN.

(1) Finding as to meaning of Colusa label.

The trial Court found (Finding No. 17) with respect to the Colusa label that:

"17. The label on each of the bottles of Colusa Natural Oil in question, when considered in its entirety, would be understood by a person of average intelligence who was suffering from one of the diseases referred to therein, and who was seeking a remedy for such disease as representing that if he would use Colusa Natural Oil as directed, that such Oil would cure or alleviate Psoriasis, Eczema, Athlete's Foot and Leg Ulcers of all types and kinds and at all stages thereof." (R. 13.)

A similar Finding (No. 18, R. 13) was made as to the Colusa Capsules.

These findings are unjustifiable.

It is indisputable that the Colusa label makes no representation that this oil will cure any case of said diseases or any phase thereof. This is patent from a mere cursory reading of the label. This label plainly tells the customers that the product is "a natural unrefined petroleum oil." There is no claim that Colusa Oil is anything but this. The government's own evidence shows this is absolutely correct.

Furthermore, there is nothing on this label which would induce (or entitle) any fair minded person to believe that he was being told that this drug would be successful in his particular case, or in each and every type or phase of said diseases. To the contrary, the ordinary person would simply conclude that this drug was being recommended as a possible aid in the treatment of his affliction, but without any particular warranty or guarantee of success in his particular case.

This is the only fair and proper interpretation which can reasonably be put upon this labeling, and to try to interpret it, as the trial judge did, as a representation that the drug *would be effective in all cases and all phases is, we respectfully submit, with all due deference, unsound and indefensible.*

Such an interpretation of labeling would bar from the shelves of the American drug stores and drug houses most of the drugs and medicinal preparations now available to the American people.

It is common sense, of course, that no drug is a "sure-shot" cure-all, effective in each and every case and phase

of the disease for which it is used or recommended. If it succeeds in curing or substantially alleviating a relatively small percentage of the cases in which it is used, it is a decidedly valuable therapeutic agency. This is particularly true of drugs employed in connection with the baffling and difficult skin diseases with which we are concerned in this case.

And, in this connection, let us emphasize that the record herein (both the government's evidence and the intervener's evidence) clearly shows that the various "standard" remedies presently employed by medical men (including the government's experts) to treat these diseases (crude coal tar, cottonseed oil, etc., etc.) help in but a small percentage of these cases.

The true rule governing such matters is that the Court should test the language employed in such a label in the light of its effect upon a person of normal intelligence and that the fair and ordinary meaning of the words employed is to govern. The following statements in prior food and drug cases dealing with labeling aptly epitomize the situation in our case:

> "The court has the right to presume that the purchasers are of average intelligence * * *" (*U. S. v. 397 cases etc. of Salad Oil,* 16 F. Supp. 387, 388.

> "Looking at the container, it is incredible that anyone of fair intelligence could be deceived into thinking, etc. * * *" (*U. S. v. 52 one-gallon cans, etc.,* 16 F. Supp. 385, 386.)

Similarly, it is incredible, we respectfully submit, that any person of fair intelligence could or would be deceived by this Colusa label.

Incidentally, it is quite significant, we believe, that the Food & Drug agents were unable to produce *one* "deceived" or "dissatisfied" Colusa customer from among the multitude of American citizens who have used this oil.

(2) Finding that Colusa oil is worthless.

This finding is patently contrary to the great weight of the evidence in this case.

The weight of the evidence below.

Even a cursory review of the record below will readily reveal, we respectfully submit, that *the great weight of the evidence was in favor of petitioner and against the government;* that petitioner's evidence consisted of a mass of undisputed and uncontradicted *factual* evidence clearly showing the efficacy of this oil; and that the government's entire case consisted of the testimony of a few so-called "expert" witnesses giving "opinion" evidence. In short, Colusa's case is one of *fact,* abundantly demonstrated below by a wealth of "human experience" and *factual data* narrated by many witnesses (medical experts and laymen) whose veracity, sincerity and knowledge were so apparent and unquestionable that the government did not even attempt to impeach a line of their testimony. The government's case is one of *"theory"* consisting essentially of "opinions" from three medical doctors.

Furthermore, the testimony of the medical witnesses below (both for the government and petitioner) clearly shows that this "opinion" testimony concerned diseases as to which medical science *is admittedly very deficient.* The record below plainly shows that the skin diseases

involved in this case are among the most baffling and difficult diseases known to medical science. The medical profession (including its specialists) has no adequate knowledge or comprehension of these afflictions (it does not even know the cause of some of them); nor any really effective and dependable treatment therefor. In treating these diseases, the profession is largely groping in the dark by a trial and error process of elimination. We mention this with no thought of disparaging the medical profession. It simply happens that as to these diseases its knowledge and treatments are presently admittedly deficient.

The situation in this case is, we believe, analogous to (but far stronger than) that presented to this Honorable Court in *Bene v. Jeantet,* 129 U.S. 683, 9 S.Ct. 428, 32 L.Ed. 803, in which the Court had occasion to choose between "theory" and "fact". The litigants had each called one "expert" witness:

> "The testimony of these two witnesses is conflicting. But the testimony of Marchand relates to facts declared to be within his knowledge and experience; whilst that of Keith is largely the assertion of a theory and a presentation of arguments to show that the facts testified to by Marchand cannot exist . . . We think the complainants did not make out a case of infringement. There is not a preponderance of the evidence in their favor." (129 U.S. at p. 688.)

The following statements from federal decisions distinguishing between "theory" and "fact" are apposite on this phase:

> "More weight is given to the testimony of a witness based upon facts within his own knowledge and ex-

perience than to testimony of a witness which is 'largely the assertion of a theory'." (*Overweight Counterbalance Elevator Co. v. Improved Order of Red Men etc.* (CCA 9) 94 Fed. 155, 161.)

"Defendant's experts, Karapetoff and Kelley, had never heard the Stentor product in operation. Their testimony was to the effect that the Stentor device would not work in any mechanism. Yet they were faced with the evidence that defendant had sold $1,000,000 worth of these devices through the years." (*Stentor Electric Mfg. Co. v. Klaxon Co.* (DC-Del) 30 Fed. Supp. 425, at 430.)

Also pertinent to this phase are the following:

AUTHORITIES AS TO THE INHERENT WEAKNESS OF "EXPERT" TESTIMONY.

American Courts have repeatedly stressed the inherent dangers in and weakness of "expert" testimony. A few typical expressions from the decisions are:

"Expert testimony is regarded by the law as the weakest character of testimony." (*Kentucky Traction & Terminal Co. v. Humphrey,* 182 S.W. 854, 856.)

"Such testimony, as has often been held, is of the weakest character and should be received and weighed with great caution." (*Strode v. Strode,* 240 S.W. 368.)

The *rationale* underlying the widespread mistrust of "expert" testimony is well summed up in *Corpus Juris* as follows:

"*Judgment of Expert.* The general uncertainty and persistent disagreement of authority on many lines of professional and scientific inquiry, the fact that this class of evidence deals so largely with the problematical and the conjectural, and the consideration that there are other elements of unreliability

arising from human frailty, bias, loyalty to one's employer, pride of opinion, self-interest, or the heat engendered by controversy, which more or less unconsciously warp the mind of the witness, even without the more vulgar elements of venality and the absence of any efficient punishment for perjury, have caused courts of the highest eminence to feel that experts are frequently rather the hired advocates of the parties than men of science placing their special experience at the service of the cause of justice. These considerations have caused the courts to characterize this class of evidence unfavorably as rather unreliable, not of great probative force, weakest and most unreliable, the weakest character of testimony, the lowest order of evidence, the lowest grade of evidence that ever comes into a court of justice, the most unsatisfactory character of evidence, wholly worthless for any judicial purpose, and of less than no value; to rule that such evidence should be received with caution, with narrow scrutiny and with much caution, and even that it should never be received at all except when absolutely necessary; and to consider that the statement of an inference or judgment is inferior in probative effect to a statement of fact." (22 *C. J.* p. 735, Sec. 825.)

The Supreme Court of Kentucky has pointed out one of the several reasons for thus condemning such "testimony":

> "One of those reasons is that the expert witness 'always colors his testimony for the side introducing him and, indeed, we learn from the history of the country that in great centers of population there exist experts following the business of bartering their expert or scientific knowledge to the litigant who can pay the highest price,' * * * etc." (*Moore v. Moore* (1943), 290 Ky. 715, 162 S.W. (2d) 547, 550.)

Another important reason for distrusting such "evidence" is explained by the Supreme Court of Minnesota in *Johnson v. Great Northern R.R. Co.*, 107 Minn. 285, 119 N.W. 1061:

> "It is equally familiar that even the more highly trained specialists cannot readily distinguish some forms of actual nervous derangement from analogous physiological conditions which may have been falsely described through ignorance, or which may have resulted from conscious malingering. A fortiori, in such cases, the testimony of even a reputable practitioner is to be weighed with special care."

And, as the New York Court pointed out in *Roberts v. N. Y. Elec. Ry. Co.*, 128 N. Y. 455, 28 N.E. 486:

> "It is none the less conjecture and speculation because the expert is willing to swear to his opinion. He comes on the stand to swear in favor of the party calling him, and it may be said he always justifies by his works the faith that has been placed in him."

Such "expert opinion evidence" is, of course, an exception to the general rule:

> "Opinions, even expert opinions, are allowed by way of exception to the general rule that a witness is to give the facts observed, but not his conclusions from them, and they are to be allowed only when there is real helpfulness or a necessity to resort to them." (*Hamilton v. U. S.* (C.C.A. 5), 73 Fed. (2d) 357.)

In *Graney v. St. Louis etc. RR Co.*, 157 Mo. 666, 57 S.W. 276, the Supreme Court of Missouri voiced its appraisal of such evidence in forthright language which is particularly apposite in our case:

"The courts, in our opinion, have gone quite far enough in subjecting life, liberty and property of the citizen to the mere speculative opinions of men claiming to be experts in matters of science, whose confidence in many cases bears a direct similitude and ratio to their ignorance. We are not disposed to extend this doctrine into the field of hypothetical conjecture and probability. * * *"

"Of course, such testimony, to dignify it by that title, with neither knowledge nor experience on which to base it or with which to back it, is simply worthless; neither courts nor juries are required to believe it. If they do, the esophagi of their credulities must be abnormally dilated or else permanently enlarged. Opinions such as these, grounded on mere conjecture or speculation, are inadmissible. (Lawson Exp. Ev. (2d Ed.) 498 et seq., Rog. Exp. Test. (2d Ed.) pp. 33, 34, Sec. 13.)"

If ever there were a case requiring and warranting the aforementioned strong denunciation of "expert" testimony voiced by the Supreme Court of Missouri, it is, we respectfully submit, the instant cause! The Government's "opinion evidence" below was nothing more nor less than the guesses and speculations of biased medical men who made no fair or adequate tests of this oil and who admittedly knew nothing as to its composition or constituents.

(3) Finding that Colusa oil is "harmful".

The lower Court, in its Finding No. 19, found that:

"The external use by a patient will, under certain conditions, have the harmful effect of causing infection in an open sore." (R. 13.)

We attack this finding on two grounds:

Firstly—It is entirely beyond the issues in this cause. It is a purely adventitious and irrelevant finding.

Secondly—This finding is not only against the clear weight of the evidence but likewise is not supported by *any real evidence.*

(a) Irrelevancy of this finding.

The libels in this case are based solely on the ground that the Colusa labeling is false and misleading in that it allegedly represents that this oil is efficacious in the treatment of these skin diseases, whereas it allegedly is not efficacious. (R. 3.) There is no allegation or charge that this oil is "dangerous or harmful". In other words, these libels purport to allege a "misbranding" under Section 502(a) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. 352-a), which reads:

> "Sec. 502. A drug or device shall be deemed to be misbranded:
>
> (a) If its labeling is false or misleading in any particular."

and do not purport to charge a misbranding under Section 502(j) which reads:

> "(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof."

It is settled, of course, that the government must allege in its libel the facts showing the alleged misbranding and it will not be permitted to allege one "misbranding" and prove another. In *Lexington Mill & Elevator Co. v. U. S.*, 202 Fed. 615, this rule of law was tersely enunciated:

> "A libel charging a misbranding of an article of food in a specified particular cannot be supported by evidence of misbranding in a different particular."

Therefore, the aforementioned adventitious finding of the lower Court as to "harmfulness" is not legally proper.

(b) This finding is against evidence.

It flies squarely in the face of an abundance of uncontradicted factual evidence which shows that this drug is not harmful. This evidence consists not only of the testimony of the many lay witnesses who told of their own use of this drug (not only with *no harmful results* but with real beneficial results) but also of the testimony of the many medical men who testified as to their successful and extended use of this drug in their practices:

Dr. Vincent (R. 66) (who has used this oil with great success in treating hundreds of cases of these skin diseases over a period of eight years) testified:

> "In the use of Colusa Oil in the hundreds of cases I have used it in over 8 years, I have never observed any adverse results from its use." (R. 74.)

> "Q. In your experience using Colusa Natural Oil and Colusa Natural Oil Capsules, did you ever observe any harmful or toxic effects from either of them? A. No, I have taken these personally for several weeks at a time, and I have had no ill effects." (*Dr. P. D. Stout,* R. 99.)

> "I observed no harmful or toxic effects from them." (*Dr. Robert L. Stokes,* R. 103.)

> "In my experience using Colusa Natural Oil and Capsules I have never observed any harmful or toxic

effects from either of them." (*Dr. Y. R. Coleman,* R. 104.)

"I have not observed any harmful or toxic effects from either of these products." (*Dr. A. H. McRuffin,* R. 106.)

"Never observed any harmful or toxic effects whatever." (*Dr. Noah W. Fountain,* R. 107.)

"I observed no harmful or toxic effects from either Colusa Oil or Colusa tablets whatever." (*Dr. E. R. Earle,* R. 118.)

"Have observed no harmful or toxic effects from the use of Colusa Natural Oil in my experience." (*Dr. Warren S. Moore,* R. 120.)

"I have observed no harmful effects whatever from the use of Colusa Oil or Colusa capsules." (*Dr. Raymond C. Morse,* R. 135.)

"I observed no harmful or toxic effects from either of them." (*Dr. Charles Wagner,* R. 148.)

"I have never observed any harmful or toxic effects from either of them." (*Dr. Harry W. Edgerton,* R. 149.)

"I have never observed any harmful or toxic effects from either of them." (*Dr. Francis A. Whiteman,* R. 156.)

"Have never observed any harmful or toxic effects from either of them." (*Dr. Michael Rabe,* R. 158.)

The sole and only pretended or alleged *factual* "evidence" which any one could point to in support of this particular finding of "harmfulness" is a vague and wholly unsubstantiated "guess" of Dr. Carney in connection with one of his so-called clinical cases (Patient No. 2 (unnamed) (R. 54)).

V. THE LIBELS DO NOT STATE FACTS SUFFICIENT TO SHOW A MISBRANDING UNDER THE FEDERAL FOOD & DRUG LAW.

(A) THE LAW.

It is well settled, of course, that:

> "A libel to condemn goods on the ground of misbranding should set forth the brand used and the facts necessary to show its falsity or misleading character." (36 C.J.S. p. 1099, Sec. 54.)

The following cases exemplify the enforcement of this rule of law, viz.:

U. S. v. 650 cases, etc. (D.C. Rhode Island), 166 Fed. 773;

U. S. v. 46 Packages, etc. (D.C. S.D. Ohio), 183 Fed. 642.

U. S. v. 650 cases, etc., supra, well exemplifies the extent to which a federal Court should go in the discharge of its important duty of protecting the property and rights of a citizen in these Food & Drug cases. That case was a libel proceeding to condemn certain bottles of catsup on the ground that they were misbranded because the label represented that this catsup was made "from choice ripe tomatoes" whereas in truth the catsup was made from tomato pulp, the waste or "offal" from tomato canning factories. The Court, in rejecting this libel as insufficient and indefinite, stated:

> "Where the charge is misbranding, it is essential that the libel should set forth the branding and the facts inconsistent therewith." (166 Fed. at 775.)

It should also be noted that in this case the owner of the goods apparently was willing to let the matter go by default rather than suffer the expense of fighting the

Government. However, the federal judge, in the discharge of his aforementioned important constitutional duty, refused to be controlled by this attitude of the owner:

> "I consider it to be the duty of the Court, before condemning property, to see that there is a proper basis for such condemnation, and this duty is not changed by the concession of the defendant that it would rather its property be condemned than that it should be put to the expense of contesting the matter with the government." (166 Fed. at 776.)

(B) APPLICATION OF SAID LEGAL PRINCIPLE TO OUR CASE.

It is elementary that to constitute misbranding under the Federal Food & Drug Act, the misbranding must occur in interstate commerce.

An examination of the libel herein involved (R. 2-4) will show that there is no allegation therein that the bottles of Colusa had on them the labels in question *when said oil was shipped in interstate commerce.* In this connection, it should be noted that paragraph 3 of the libel (R. 2) starts with a pure conclusion of law (i.e., that these Colusa products were misbranded in interstate commerce) and then speaks *not* of the date or time of shipment in interstate commerce but of the present time (i.e., the time of the filing of the libel) when it states:

> "* * * in that the following statements which *appear* in the labeling of the articles * * * *are* false and misleading" etc. (R. 3.)

In short, no *facts* are alleged to show that a misbranding occurred while these goods were in interstate commerce.

The following language in *U. S. v. Research Laboratories,* 9 Cir., 126 F. (2d) 42, succinctly describes the libel herein:

> "The libel is crudely and inexpertly drawn." (at 44.)

In our case, there are no "saving" allegations such as the Court adverted to in the Ninth Circuit in holding that libel not to be fatally defective.

WHEREFORE, it is respectfully submitted that this petition for certiorari should be granted.

Dated, Washington, D.C.,
November 3, 1949.

WALTER M. GLEASON,
Attorney for Petitioner.

ARNOLD, FORTAS & PORTER,
Of Counsel.

(Appendix Follows.)

Appendix

PART ONE

ANALYSIS OF GOVERNMENT'S EVIDENCE BELOW

The government had a total of *nine witnesses.* The first *three* witnesses for the Government (Bauerlein, Simmons and DeNosaquo) were agents of the Food & Drug Administration, whose testimony was solely routine testimony relating to their securing and forwarding the samples of this oil which were used by the Government's "experts" in their tests of oil. (R. 22.)

The other *six* witnesses were so-called "expert" witnesses.

The first of these "experts" was *Dr. Lewis F. Hatch* (R. 22-35), an Associate Professor of Chemistry at the University of Texas, (R. 22.) *His testimony added nothing whatsoever to the Government's case.* After he had testified at length concerning various tests made by him of Colusa Oil, he ended by announcing his conclusion as follows:

> "A. I concluded that it was a natural petroleum oil, which might contain both paraffins and naphthenes, and possibly aromatic compounds." (R. 34.)

When it is recalled that the label involved in this case expressly states that Colusa Oil is a "natural unrefined petroleum oil" (R. 3) and that the parties had expressly stipulated that this was so (Gov. #100, R. 22), the futility of this lengthy testimony of Dr. Hatch becomes, we believe, apparent. This becomes even more apparent when the cross-examination of this witness is considered. He then was forced to admit that *he did not know what the constituents of this oil were, and that he had made no tests to determine whether it is a paraffin base oil, an asphalt oil or a mixture of the two.* (R. 29.)

Furthermore, his cross-examination clearly developed the fact that any single petroleum oil is a *most complex mixture of complicated chemical compounds;* and that to

accurately break down and analyze a single sample of such an oil in order to determine all of its constituents would require *years* of detailed tests and analysis. (R. 28.) This witness spent not over a total of 24 *hours* on his tests of Colusa Oil. (R. 29.)

The next witness for the Government was *Dr. Irwin G. Gross* (R. 34-35), a Professor of Pharmacology from the University of Iowa. This "expert" voiced the opinion that "there is no pharmacological basis for the use of crude oil as beneficial action." (R. 35.) This witness did not claim or purport to have the *slightest knowledge of, or experience with, Colusa Oil.* Furthermore, the worthlessness of his blanket condemnation of *all* crude oils from a therapeutic standpoint becomes manifest, we believe, when it is realized that there are thousands upon thousands of different crude oils; and that from such oils are derived a host of important and valuable medicinal products now in daily use by the medical profession. (p. xxvi infra.) Furthermore, the record herein shows that from a crude oil shale found in the Austrian Tyrol (and in a few other places in the world) there is produced the exceptional medicinal product known as ichthyol, the therapeutic value of which in the medical world is now unquestioned. Moreover, the record herein plainly shows that even the Government's own so-called "experts" employ as a regular and important part of their therapy, in the treatment of these very skin diseases, *"crude coal tar,"* which, as a member of the hydro-carbon family, is directly related to crude petroleum oil. (R. 129.)

For the foregoing reasons, the unsubstantiated "opinion evidence" of Dr. Gross, who knew nothing about Colusa Oil or its constituents, added nothing to the Government's case. To the contrary, his testimony aided appellant because he admitted that "crude oil applied to the skin would act as an emollient. It would soften the skin." (R. 35.) As the record shows, this "emollient" result is an important part of the healing process. (R. 72.)

Another of the Government "experts" was *Dr. Charles M. Brewer* (R. 43-48), a bacteriologist for the Food & Drug Administration at Washington, D. C., who testified that he made certain tests of Colusa Oil to deter-

mine whether it had any bactericidal, fungicidal, bacteriostatic or fungistatic properties. After describing these tests (R. 44), he voiced his "opinions" that these Colusa products had neither germicidal, or fungicidal, fungistatic or bacteriostatic properties. (R. 45-46.)

In view of the fact that the medical profession does not know what causes psoriasis (i.e. whether caused by germs, fungi or other agents), and knows almost as little concerning these other skin diseases, the unimportance of the testimony of this "expert" needs, we believe, no extended discussion.

This witness made no tests of any kind of the use of Colusa Oil in the treatment of any of the skin diseases involved in this case, or any other diseases whatsoever. His brief cross-examination shows, we believe, the insignificance and irrelevancy of his testimony insofar as the real issues in this cause are concerned:

> "I have never heard of fungus causing psoriasis. I do not know if germs cause psoriasis." (R. 48.)

Thus far, we have discussed the testimony of *six* of the *nine* witnesses whose testimony constituted the entire case of the Government. The remaining *three* witnesses were medical doctors whose testimony was the *only* testimony offered by the Government on the vital subject of the actual use and efficacy of this oil in the treatment of the skin diseases involved in this case.

The first of these three doctors was:

Dr. Adolph Rostenberg (R. 35-43) (SR. 2-43), an Associate Professor of Dermatology of the University of Illinois and a former medical officer for the federal Food & Drug Administration (1939-1945) (R. 36). This witness, the principal witness for the Government, testified at length as to the nature, causes and treatment of these various skin diseases (psoriasis, eczema, leg ulcers, athlete's foot). (R. 37-38) SR. 2-21). Insofar as the fundamental issue as to the efficacy of Colusa Oil is concerned, his testimony consisted of two principal phases:

In the first place, testifying as an "expert", he voiced the opinion that Colusa Oil is not an effective or appro-

priate treatment for *all* phases and types of these several skin diseases.

Secondly, he described some so-called "clinical" tests allegedly made by him of Colusa Oil in the treatment of these several skin diseases.

(A) *The so-called clinical tests made by Dr. Rostenberg of Colusa Oil and Capsules.*

These tests were allegedly made by him at the Dermatological Clinic of the Research and Educational Hospital of the University of Chicago. He stated that he used Colusa Oil and Capsules on *four* patients attending this clinic for treatment of their skin diseases, and that he also used the oil on himself.

These Rostenberg "clinical tests" of Colusa Oil were wholly inadequate and unscientific, both from the standpoint of time and method. Under no proper concept could they be classified as reliable "evidence". Dr. Rostenberg selected extremely complicated cases of these skin diseases (cases which normally would take many weeks, if not months, to materially improve) and used (?) Colusa Oil for but *a few days* on these severe skin scourges.

We will now undertake to briefly show the soundness of the foregoing criticisms of these Rostenberg "clinical tests".

In the first place, it should be noted that this "scientist", who had at his command a first-class clinic with many hospital patients (i.e. bed patients), selected for these "tests", *ambulatory* cases:

> "I did not test Colusa Oil on any bed patients." (R. 41.)

Obviously, as the record shows, the witness had no real or adequate *control* over (or opportunity to properly observe) these ambulatory cases during these so-called "tests". His testimony shows that he met them for a few minutes at the clinic, made a quick observation of their skin ailments, gave them this Colusa Oil and told them to use it *at home* according to the directions on the label. (R. 39.)

He did not even see them use the oil or apply it and he did not even know, of his own knowledge, whether or not these patients ever did apply the oil! Or whether, if they did, they used the drug in accordance with the instructions on the label!

"Mr. Gleason: You didn't apply the drug, Doctor?

Witness Rostenberg: I gave them the drug, read them the directions the same as I give any other drug, and told them to use the drug at home according to the label on the packages I received. I did not put it on with my own hands, no.

Mr. Gleason: Did you see it put on?

Witness Rostenberg: No." (SR. 23.)

This witness was, of course, well aware of the elementary first principle and basic requisite of any such a "test", that is: "*It must be a carefully controlled test.*" In other words, to be of any value whatsoever (either scientific or legal), such clinical testing requires, as its primary element, that the doctor or other observer carefully and continuously control and observe every step and phase of the test. Dr. Rostenberg blandly admitted that he made no effort whatsoever to comply with this basic requisite!

Yet it is upon the basis of such flimsy and unscientific "evidence" that the Government seeks to have a citizen's property seized and his business destroyed, and to deprive the American people of the opportunity to use this medicinal oil, which unquestionably has done a vast amount of good in the treatment of these skin diseases.

Going further with the analysis of this "expert's" testimony, we find that notwithstanding it is indisputable that the skin diseases involved in this case are among the most baffling and stubborn diseases known to the medical profession, and that even with the best of luck and treatment the cure or substantial alleviation thereof generally requires weeks and months of treatment, nevertheless, in these so-called "clinical tests" of Dr. Rostenberg, Colusa Oil was used (if it was used) by these ambulatory patients *for but a few days*. When this fact is coupled with the further indisputable fact that this "expert"

selected *very severe and complicated cases of these skin diseases*, the weakness of this so-called "evidence" becomes, we believe, even more apparent. In fact, some of these patients were suffering from not only *one* skin disease, but a complication of *several* different skin diseases superimposed one on top of the other.

Details re these Rostenberg tests.

The first patient, Mr. T. Smith, suffered from two different skin diseases at the same time, superimposed upon each other:

> "He had an irritating tinea cruris and a mild dermatitis venenata, two different skin diseases at the same time and in the same place." (R. 42) (SR. 34.)

The doctor first saw him, for 15 or 20 minutes, on September 29th; observed these complicated skin diseases; gave him the oil; and then next saw him for the second and last time on October 9th, at which time, noting no improvement, he instructed him to discontinue the use of the oil.

Then a strange thing happened!

This "scientist" thereupon apparently lost all interest in this patient! (R. 42.) How incredible! Here is a poor, unfortunate sufferer seeking relief at this clinic. When Colusa Oil allegedly fails to help him, this "expert" (who, in his direct examination, dwelt at length upon his profound knowledge of these diseases and of the various methods used by him in their cure) *did not even try to further treat or alleviate Mr. Smith's skin ailments. Why didn't he at least try some of his other therapy, and thereby put himself in a position to, in good faith, report the results thereof in this case to the Court!* We believe the reason is apparent.

The second patient of Dr. Rostenberg (E. G. Funk) was suffering from a severe case of psoriasis which covered most of his body (R. 39), and in addition thereto, a tinea cruris with a secondary eczematous condition. Yet this oil was used (if it was used) for but a few days:

> "I read the label to the patient and told him to use it. He returned in *two* days claiming his crotch

was much more irritated. I discontinued the oil for the crotch but told him to continue the Colusa Oil on the lesions of the psoriasis and to continue the oil internally. I gave him a soothing lotion and saw him about *five* days after that, at which time his crotch was considerably better. As to the psoriasis, the oil had facilitated in removing some of the scales from the psoriatic lesions, but the essential lesions of the psoriasis were unchanged. *I did not see the patient after that.*" (R. 39) (SR. 26.)

When it is realized that psoriasis is a disease the cause of which ethical doctors frankly admit they do not know, and for which they have no really effective treatment or cure, and which, in practically every instance, has a prognosis and runs a course of many months, the aforesaid Rostenberg performance of using the oil for only a few days, and yet expecting to see a clearing up of the psoriatic lesions is, we respectfully submit, little short of fatuous.

Even Dr. Rostenberg had to admit on cross-examination:

> "The medical profession does not claim to know the causes of psoriasis, nor to permanently remove psoriasis." (R. 41.)

Dr. Vincent clearly exposed the fallacy of the aforementioned Rostenberg "test case":

> "Psoriasis and eczema are generally of long standing, their courses run over a period of months and years sometimes. I certainly would not expect to produce a cure or to materially improve such a condition of the disease in three to five days." (R. 73.)

> "Assuming that a man had a case of psoriasis, moderately generalized over his body in addition to an eczema in the groin, and that a particular medicine was given him on one day and that five days later I observed the patient and saw no material improvement, no change, that would not be sufficient to enable me to arrive at a judgment as to the efficacy of that remedy." (R. 74.)

In fact, Dr. Rostenberg had to admit on cross-examination that even as to "eczema" *alone:*

> "the range for eczema cases may be from two weeks to years." (R. 43) (SR. 41.)

and that as to psoriasis:

> "Lesions from psoriasis may last for several years. We have cases, I am sure, who have had intermittently lesions of psoriasis for many, many years." (R. 43) (SR. 41.)

And yet, in this extremely difficult case of Mr. Funk, (a severe case of psoriasis complicated by a "secondary" eczematous condition), the oil was used (if it was used) for but *five days!*

The third patient (Jane Kelly) "treated" by this scientist was in an even worse condition of skin complications:

> "She had ulcers on both legs, which arose on the basis of the varicose veins she had. She had a stasis eczema plus a superimposed pyogenic infection, and the combination of the two gave her these bilaterations." (R. 39) (SR. 27.)

Yet this patient was "treated" for but *one week!* (R. 40.) He first prescribed Colusa for her on September 8th and next saw her on September 15th, at which date he:

> "* * * turned her over to somebody else at the Clinic after telling her to discontinue Colusa." (R. 42) (SR. 38.)

Again we ask: "Why this sudden dropping of the patient in this 'scientific' test?" We believe it is evident that the doctor did not want to run the risk of building a further record of treatment which would disclose that these clinical cases thus "tested" by him were so serious and complicated that, by the use of *all* the medicines, methods and therapy known to him and the science of dermatology, it would probably take months to clear up or materially improve such cases! Yet Colusa was used for but a few days!

Furthermore, why didn't this "scientist" continue to keep these "test cases" under observation *for at least a reasonable time after the use of Colusa Oil,* to determine whether or not the previous use of this oil during the period in question might not reflect itself in an improvement first becoming manifest *after* the actual use of the drug has ceased? As is obvious (and as Dr. Vincent emphasized), the results of the use of a medicine to treat a skin or other disease during a particular limited period of days might not show up until *after* the actual use of the drug had ceased:

> "All the results of that treatment in that period of time could not be seen and observed. You cannot set the time you expect to see the result of treatment because every patient has to react." (Dr. Vincent, R. 73.)

The last of these clinic patients thus "treated" by Dr. Rostenberg (Theodore Bednar) also suffered from a complication of several skin ailments, viz.:

> "He had several conditions, the first of which was a condition, a form of eczema, which is called lichen simplex chronicus, a form of eczema, also stasis dermatitis, it had not reached ulceration, it was in the ezcema stage. He finally had chronic infection of several toenails, athlete's foot infection." (R. 40) (SR. 30.)

He too was "treated" for but a week and then the Doctor switched the therapy. To what? *To a crude coal tar ointment!*

> "I couldn't give you the chemistry of coal tar, I don't know. Just how it is obtained, I don't know. I guess our sulfa drugs come from that base by a very devious route." (R. 42) (SR. 39.)

(B) *The "opinion" evidence of Dr. Rostenberg.*

The "opinions" of this witness as to the lack of efficacy of Colusa Oil were phrased as follows:

> "Based on my knowledge, training and experience in the field of dermatology, crude petroleum oil ap-

plied externally or used internally or used in combination is not an appropriate and effective treatment in *all* types of eczema." (R. 37) (SR. 7.)

"In my opinion, Colusa Natural Oil when taken as directed on the label would not be an appropriate and effective treatment for *all* types of psoriasis." (R. 38) (SR. 12.)

"My opinion is that the two remedies" (i.e. Colusa Natural Oil and Colusa Capsules) "in question, singly or together, would not be an effective remedy for *all* types of leg ulcers." (R. 38) (SR. 17.)

"In my opinion Colusa Natural Oil would not be an effective remedy for *all* types of athlete's foot either when used alone or in combination with the capsules." (R. 39) (SR. 22.)

This same witness admitted:

"I do not know of any drug that is an appropriate and effective treatment for *all* types of eczema in all stages of the disease." (R. 37) (SR. 7.)

"I do not know of any drug that is an effective and appropriate treatment for *all* types of leg ulcers." (R. 38) (SR. 16.)

"I do not know of any drug that is an appropriate treatment for *all* types of athlete's foot." (R. 39) (SR. 21.)

In other words, although medical science knows of no drug which is an adequate and effective treatment for *all* types and phases of these skin scourges, Colusa Oil apparently should be condemned because it is not effective *in each and every case and for each and every phase of these difficult diseases!* Could any "reasoning" be more illogical or unsound? The unsoundness thereof becomes even more manifest when it is realized that (as the record plainly shows) this witness (R. 41) and the other Government experts (Trunnell, R. 52; Carney, R. 57) regularly employ, in their aforementioned "trial and error" therapy, many different drugs, *not one of which is an*

adequate or effective remedy for all the types and phases of these diseases. These "remedies" are apparently successful in but a small percentage of the cases wherein they are employed. Why, may we respectfully ask, do not Dr. Rostenberg and his associates discard and condemn these other "standard" remedies (crude coal tar, cottonseed oil, petroleum jellies, etc., etc.) if Colusa Oil is to be condemned because it does not work in *all* cases and phases of these baffling diseases? The law, of course, does not support or sanction any such an erroneous theory of "efficacy".

These carefully restricted "opinions" of Dr. Rostenberg are, therefore, of no importance or value herein.

Likewise valueless and unsubstantiated are his "opinions", based upon his so-called clinical tests, that Colusa Oil and capsules, when taken in combination, would be "worthless" in the treatment of these several diseases; and that Colusa Oil would be of no value in treating athlete's foot. (R. 40.)

The next witness for the Government was *Dr. Thomas L. Trunnell* (R. 48), a young dermatologist practicing at Waterloo, Iowa. He testified as to the use of these Colusa products in the treatment of *seven* of his *patients.*

The amazing thing about this testimony is that, although this "expert" was a practicing physician and purported to have given Colusa a fair test, in his daily practice, by trying it out on *his* patients, *these so-called patients apparently dropped completely out of sight and were not further treated by this doctor once their use of Colusa ceased!* What a peculiar practice! What evanescent patients! What a strange method of trying to cure suffering humanity!

In short, these "patients" purportedly came to this doctor to seek cures (or at least alleviation) of these horrible and painful skin diseases. He then treated them with Colusa for a few days with no results. Then what? *They disappear! He treats them no further!*

> *As to Patient No. 1* (Albert Siebrands, R. 49): "I did not use any other treatment on this patient after he had ceased using Colusa Oil and Colusa Capsules."

As to Patient No. 2 (Ruth Pook, R. 49): "I didn't see her after that."

As to Patient No. 3 (A. Larson, R. 50): "That was the last time I saw him."

As to Patient No. 5 (T. J. McLaughlin, R. 50): "I didn't treat him again."

On cross-examination, this witness admitted that when he was requested by a Food & Drug agent to make these "tests":

> "* * * he indicated my investigation was to be part of the case we are trying today." (R. 52.)

And yet, knowing this, this trained dermatologist made no effort whatsoever *to secure and compile really scientific and useful data!* Why didn't this expert (knowing that he was to be called upon to give to a Court in an important case *scientific* data) set about to really secure such data by giving Colusa Oil a fair and adequate test, and by keeping these "patients" under strict observation to ensure that this *oil* was used and used properly; and by subjecting these "patients" to the subsequent use of other treatments or drugs *in order to thereby obtain valuable comparative data as to the results; and by continuing his observation of these patients long enough to acquire a real knowledge of their afflictions, and of the effect thereon of an adequate and proper use of Colusa Oil?* On cross-examination, the doctor admitted that he normally uses a variety of remedies (including petroleum jellies) in treating these skin diseases. (R. 52.) Why didn't he use some of these remedies on these "test" cases so as to thereby secure helpful comparative data?

Or, putting it solely upon a basis of common decency and humanity (not to mention the Oath of Hippocrates), why didn't this purportedly skilled dermatologist at least make *some* effort (after the alleged failure of Colusa) *to help these poor suffering humans by alleviating or further treating these patients?*

The reason is, we believe, apparent. His purpose was that of discrediting Colusa and he studiously avoided any

subsequent treatment or case record which might discredit him instead of Colusa.

Is it any wonder that the Courts have so frequently voiced suspicion and condemnation of the testimony of such partisan witnesses as these so-called "experts"?

In concluding with this witness, it might also be noted that his alleged "tests" are subject to the same criticisms hereinabove set forth with respect to the "tests" of Dr. Rostenberg. *For example, the doctor did not even know, of his own knowledge, whether the Colusa Oil had been used at all, or whether it had been properly used.* (R. 49-51.) Furthermore, the time or duration of use (if there was a use) *was far too short to constitute any fair or adequate test.* Incidentally, this witness had to admit on cross-examination that:

> "Dermatology is not an exact science * * * There are many skin conditions, skin diseases, we don't know the cause of them exactly, but in a majority of them we probably do." (R. 52.)

It might also be noted in passing that while this Government "expert" admittedly uses a variety of drugs in the treatment of these skin diseases, none of which is an adequate remedy for all types and phases of these diseases, and while these medicines oftentimes fail to alleviate or help individual cases of these afflictions, *he continues to use them and does not discard them.* (R. 51.) Yet Colusa should be condemned because it allegedly failed to help these few complicated and difficult cases in which this expert gave it such an utterly short and inadequate trial!

The next and last witness for the Government was:

Dr. Robert G. Carney (R. 52-58), an Assistant Professor of Dermatology and Syphilology at the University of Iowa (admitted to practice in 1940, R. 53), who testified that at the request of the Food & Drug Administration he "tested" Colusa Oil by treating, at the Iowa University Hospital, *six* bed patients suffering from various skin diseases. It is respectfully submitted, with all humility, that under any fair appraisal the "evidence" produced

by this witness was plainly weak and worthless. In addition to using the oil for but a *few* days on extremely complicated and longstanding cases of these skin diseases, this "expert's" methods of treatment and his reasoning as to results were not only clearly unscientific, but little short of fatuous.

This "expert", in his "scientific" testing of Colusa Oil, resorted to *the astounding procedure of concurrently treating, for a few days, different areas of diseased skin of the same patient with different remedies and of then endeavoring to draw "comparisons" between the two "sides"*. In other words, he treated one area of diseased skin with Colusa, and the other with one of his "standard" remedies.

For example his patient #6 (Wallace Stewart, R. 56), was suffering from a severe case of psoriasis "with patches on all parts of his body." During the period *October 30th to November 6th*, Dr. Carney treated the left side of this man's body with Colusa Oil, and the right with *"plain cottonseed oil"*. Then (as of November 6th):

> "The part treated with Colusa was slightly improved at that time. The part treated with cottonseed oil was equally improved." (R. 56.)

However, notwithstanding this photo-finish in this cutaneous contest of *Colusa Oil v. Plain Cottonseed Oil*, Dr. Carney terminated this particular race on the 6th. Colusa was eliminated and the Doctor started a new combination of crude coal tar, cottonseed oil, ultra-violet, etc. (Rep. Tr. 217.) By the 12th the patient "was about 90% improved." (R. 56.) *ERGO: Colusa Oil—not good; Crude Coal Tar, et al.—good!*

What inanity! And perpetrated in the name of science! And an American Court is asked to condemn a citizen's property and destroy his business on the basis of such so-called "evidence"!

Another illuminating example of this "scientific" research conducted under this unique Carney method of comparative therapy, is Dr. Carney's Case No. 1 (John

Minner, R. 53). This patient was suffering from a severe case of eczema which covered a large part of his body. From September *15th to 20th,* the right side of this man's body was treated with Colusa Oil, the left with LaSaar's Paste. At the end of this "lengthy" contest of *Colusa Oil v. LaSaar's Paste,* Dr. Carney thought the "Colusa side" was "slightly worse," and that there was a "slight improvement" on the left (paste) side. The Doctor then called off this contest between Colusa and the paste on Mr. Minner's diseased skin surface. He discontinued Colusa on the 20th, and gave the exclusive field (right and left) to the paste, with the result:

> "Q. What was the patient's condition after the Colusa Oil was stopped?
>
> A. He made slow improvement.
>
> Q. When was the improvement noticeable?
>
> A. Within two or three days." (Rep. Tr. 205, R. 54.)

ERGO: Colusa—no good; the paste—good!

Could anything be more illogical or unscientific than this Carney procedure, and the "reasoning" underlying these Carney clinical tests?

In the first place, Dr. Carney's assumption that, because Colusa was stopped two days before the improvement was noted, it had nothing to do with this "improvement" is obviously fallacious. For all he knows, *Colusa was the responsible causative factor!* It is elementary that the results of the application of a particular drug may not become apparent until days later. Time must be allowed for the drug to accomplish its action and the patient's reaction. As Dr. Vincent expressed it:

> "All of the results of that treatment in that period of time could not be seen and observed. You cannot set the time you expect to see the result of treatment because every patient has to react." (R. 73.)

Even the ancient philosophers readily detected and labeled the fundamental fallacy which vitiates Dr. Carney's said reasoning processes, viz.:

> *"Post hoc ergo propter hoc."*

In other words, Dr. Carney implies that, because the improvement noted by him first became apparent after the cessation of the Colusa use, and after some other treatment was started, such improvement must be attributed to the second remedy and not the first. Such reasoning is, we respectfully submit, little short of puerile.

Furthermore, the sophistry of this Carney method of attempting to make comparisons between two diseased skin surfaces simultaneously treated with different remedies becomes even more apparent when it is realized that he applied it to skin ailments the underlying cause of which he knew little or nothing about. For example, he had to admit that as to psoriasis:

> "I do not know the cause of that disease." (R. 57.)

As the record plainly shows, we are dealing herein with some of the most baffling and difficult diseases known to medical science. As stated above, the ethical members of the profession frankly admit that they are largely groping in the dark in this particular realm of medical science. The causes and courses of these difficult diseases are often obscure and difficult of exact prognosis or precise determination. Internal and external causative factors and stimuli can and do continuously or intermittently interact. As Dr. Rostenberg pointed out:

> "A. The skin is one of the biggest organs of the body. It is that organ of the body which is a barrier between the internal environment and the external environment, and by virtue of acting as a buffer organ it is subject to all sorts of stimuli * * *." (SR. 4.)

And, as our Courts have pointed out, "nature" plays a vital part in any healing or curative process:

> "Nature, supplemented and aided by proper medicine, careful nursing and proper diet, does the work of curing." (*U. S. v. 23 Bottles etc.*, 44 F. (2d) 831, 835.)

Under such circumstances, for any person (scientist or otherwise) to assert or pretend that he can observe, determine or know the extent, duration and degree of the effect (or non-effect) of the use *for a few days* of Colusa

Oil on a given patch of psoriatic lesions on a patient's body, *as distinguished from some other lesions or patches on the same diseased body being concurrently treated with some other medicines*, is, we respectfully submit with all humility, little short of nonsensical.

Incidentally, it is interesting to contrast Dr. Carney's pretensions of almost "stop-watch" accuracy in detecting, evaluating and discriminating between the results of concurrent treatment of different areas of the same diseased skin with the following contradictory findings of the lower Court that:

> "The causative factor or factors of Psoriasis are obscure and difficult of ascertainment. Psoriasis is a very difficult and frequently baffling disease to treat. Manifestations of the disease will appear and disappear without any apparent reason or cause." (Finding No. 12, R. 11.)
>
> "There are a great many types of Eczema and many causes for it. There are different stages of the disease. In some cases of Eczema the causative factor or factors are easily ascertained. In other cases of Eczema the causative factor or factors cannot be ascertained. In cases of Eczema where the causative factor or factors are unknown, they may cease, and the disease cease without the patient or his doctor being aware of what brought about the cessation of the disease. In the cases of Eczema where the causative factor or factors are unknown, they may become inactive or less active and the patient may have a partial cure or have relief without the patient or his doctor being aware of what brought about such partial cure or relief." (Finding No. 13, R. 11-12.)
>
> "In a great many cases the causative factor or factors of Leg Ulcers are difficult of ascertainment. In a great many cases of Leg Ulcers the causative factor or factors cannot be ascertained."
>
> "Where the causative factor or factors of Leg Ulcers are unknown, they may cease and the disease cease without the patient or his doctor being aware of what brought about a cessation of the disease.

> Where the causative factor or factors of Leg Ulcers are unknown, they may become inactive or less active and the patient may have a partial cure or have relief without the patient or his doctor being aware of what brought about such partial cure or relief." (Finding No. 14, R. 12.)

In short, the Court says, in effect, that Dr. Carney couldn't accurately detect or observe or know that which he claims to be able to do, as aforesaid! In other words, the lower Court's "theory" of unpredictable mutations in the diseased skin surfaces doesn't square very well with the basic premise underlying this unique Carney system of simultaneous skin strip therapy.

In addition to the foregoing basic shortcomings, Dr. Carney's "evidence" is subject to the further criticism that his "factual" deductions were not even sound. In other words, he did not even properly understand or evaluate the physical facts observed by him in these inadequate and unscientific clinical tests. For example, in the aforementioned case of *Colusa Oil v. LaSaar's Paste* (Case #1), this scientist gave the paste a slight edge because he noted that the "Colusa side" of the patient's body had increased in "redness," and he apparently considered that this was an *unfavorable* sign. The simple truth is that such "redness" is a first sign of improvement. The factual evidence in the record below clearly shows that one of the initial signs of betterment in these cases is a reddening of the skin accompanied by a gradual clearing up of the lesions and incrustations of the diseased skin surface.

Dr. Vincent, who has treated hundreds upon hundreds of cases of these skin diseases, succinctly exposed the fallacy of Dr. Carney's thinking on this phase:

> "Redness is only an indication of the usual thing. After there has been an eruptive condition removed from the surface, the remaining redness is simply a part of the healing." (R. 72.)

> "The fact that there has been an increase in the redness of the skin during that short period of time

would lead me to believe that the patient was better. I have never seen a case that you didn't find an increase in the redness after removing the scales." (R. 72.)

Curiously enough, however, Dr. Carney, on cross-examination, unwittingly admitted the inevitability and favorableness of such redness in psoriasis cases:

"Q. When you as a dermatologist attack that disease one of your objectives is to eliminate these scales, is that right?

A. Remove them.

Q. Yes, remove them?

A. Yes.

Q. When you remove them, what is the color of the skin?

A. Red." (Rep. Tr. p. 231.)

The case histories of various intervener's witnesses confirm this by cogent *factual* evidence.

Another illustration of the fallacious reasoning (and lack of knowledge of elementary medical facts) on the part of Dr. Carney is his Case No. 4 (Stella Jackson, R. 55). This patient, a lady of 88 years, was suffering from a severe leg ulcer (stasis ulcer), no doubt of long standing. Colusa Oil was used in this case for *three days!* The doctor testified that during this period there was a "copious bluish green discharge of pus." (R. 55.) Dr. Carney apparently considered this an unfavorable sign. The truth, however, is that this is an early indication of improvement:

"Pus or exudation from the ulcer is the infection coming through, it is not unusual, many ulcers have it, it is one of nature's healing methods, throwing off the infection." (Dr. Vincent, R. 73.)

Various of the leg ulcer cases described in detail in the defense testimony show that one of the early effects of the use of Colusa Oil on leg ulcers is a fairly prompt cessation of "pus" exudation:

"After I used Colusa Oil I noticed that the discharge had stopped right away; it was a couple of days that I noticed it didn't discharge." (Mrs. Goranson, R. 110.)

"I was like a leper with those two legs * * * the stench was abominable * * * they were covered with pus and they were positively rotting on me * * * When I started using Colusa Oil my legs were completely covered with sores, they were putrid at the time and the smell was terrific. I started to use it in the early part of December and on the 5th of January, 1942, I was thoroughly cured of it." (Mrs. Loughran, R. 93.)

And yet Dr. Carney, in this Stella Jackson case, would have us believe that he concluded that because *two* days elapsed between the cessation of the use of Colusa and the stopping of the pus exudation, there was no causal or other relationship between these two events!

In addition to being based on the aforementioned fallacious reasoning and erroneous interpretation of the physical observations, these so-called clinical tests of Dr. Carney were entirely inadequate and unfair insofar as *the duration* thereof is concerned. The time thereof was obviously *far too short*. Here again we find the Government's partisan "expert" intentionally selecting extremely difficult and complicated cases and of then treating them for but a few days. For example, let us take Dr. Carney's Case #5 (Hjelmar Hendrickson, R. 56). Dr. Carney treated this man for but *three* days by his aforementioned unique system of therapy. Yet this poor skin sufferer, whose body was a mass of psoriatic lesions on every part of his body (an "extremely severe case" R. 56) had, according to Dr. Carney's admissions on cross-examination, *been afflicted with this disease ever since 1922 and had treated at this very clinic since 1934.*

And yet Dr. Carney suggests or implies that Colusa Oil should be condemned because it did not clear up this mass of repulsive flesh in three days!

Even he, however, had to admit, on cross-examination, that:

> "I do not expect an improvement necessarily in three days after applying medication in a case of psoriasis." (R. 58.)

Another illustrative example of the ridiculously short duration of these so-called tests of Colusa is Dr. Carney's case #4 (Stella Jackson). This woman, suffering from a large and severe leg ulcer, was treated for 3 days!

Could anything be more unfair, inadequate and unscientific than this *three day* test on a long standing and severe leg ulcer!

Incidentally, it is interesting to note that as of the date of the trial of this case (November 13-18, 1947), Dr. Carney's Patient #5 (Hendrickson), was still suffering from his disease and *was still a patient at this hospital.* (R. 58.) May we be pardoned for asking as to what happened to the other half of the Carney dual therapy—cottonseed oil? Why didn't it clear up this case? Or, to take the other tack, why didn't Dr. Carney, to be consistent, discard his supply of cottonseed oil when, *over thirty days after its three day cutaneous contest with Colusa, cottonseed was still waging a losing battle with Mr. Hendrickson's psoriatic lesions!*

So much, therefore, for these Carney clinical tests. We respectfully submit that these so-called clinical tests, with their Carney concurrent cutaneous contests between Colusa Oil, Cottonseed Oil, Crude Coal Tar, etc. etc., are worthless and do not even approach the status of dependable or reliable factual evidence.

We will now briefly discuss the

Expert Opinions of Dr. Carney.

The "opinions" of this expert as to the "efficacy" of Colusa Oil were voiced in the same peculiar and limited manner as is pointed out hereinabove with respect to Dr. Rostenberg, viz.:

"In my opinion, Colusa Oil is not of value as an appropriate and effective treatment for *all* types of eczema." (R. 57.)

"In my opinion Colusa Natural Oil and Colusa Natural Oil Capsules when used singly or in combination is of no value in the treatment of *all* types of leg ulcers." (R. 57.)

etc., etc.

Yet, here again we find the "expert" admitting:

"I know of no drug that is an appropriate and effective treatment for *all* types of psoriasis in all stages of the disease." (R. 56.)

"I do not know of any drug that is an appropriate and effective treatment for *all* types of eczema in all stages of the disease." (R. 56.)

"I know of no drug that is an appropriate and effective treatment for *all* types of leg ulcers." (R. 57.)

"I know of no drug that is an appropriate and effective treatment for *all* types of athlete's foot." (R. 57.)

On cross-examination, he further admitted that while he and his fellow practitioners use "roughly 20 to 30 medicines" (crude coal tar, cottonseed oil, ichthyol ointments, zinc oxide, etc., etc.) in their efforts to treat these several skin diseases:

"None of them is an appropriate and effective remedy for all types of psoriasis, or eczema, or athlete's foot, or skin ulcers." (R. 57.)

Why doesn't this expert condemn and quit using these 20 to 30 remedies *because they admittedly do not work in ALL cases and phases of these diseases!* In other words, Colusa is to be condemned because (as these experts view it and the trial judge concluded), it is not efficacious in *all* cases and phases of these several diseases, yet these other remedies (which admittedly are similarly limited in

that they are not efficacious for all stages and phases) *are perfectly proper and should be protected!* In other words, it is perfectly proper to distribute in the American drug stores and drug dispensaries (or otherwise) these 20 to 30 "standard" remedies (Crude Coal Tar, petroleum jellies, etc.) even though they are effective in but a small percentage of these cases, yet Colusa must be denounced, condemned and banished because it is not a "cure-all."

What logic!

It is common sense, of course, that if said test and reasoning employed by these so-called experts (and followed by the court below) were a sound criterion, practically no drug would be left on the shelves of our American drug stores or drug dispensaries. *No drug is effective for all stages and phases of a given disease.* If it cures or materially alleviates in a relatively small percentage of the cases where it is used, it is a boon to medical science and suffering humanity! The courts have had occasion to emphasize these elementary principles of medical science:

> "The testimony of the experts shows that a therapeutic or curative agent is something which alleviates or tends to cure a disease, and that, except in a few instances, there is no medicine which, of itself, is an absolute cure for diseases. * * *" (*U. S. v. 23 Bottles*, 44 F. (2d) 831.)

Incidentally, it is interesting to note that Dr. Carney admitted that before he ever started these "tests" of Colusa Oil he had a fixed opinion (prejudice) that no crude petroleum oil would be of any value in the treatment of these skin diseases. (R. 57.) In short, this "disinterested" scientist, by his aforementioned dual therapy, found the result he was looking for.

Furthermore, while this witness was quite ready and free with his sweeping and smug opinions that neither Colusa Oil or any other petroleum oil had any efficacy in the treatment of these diseases, he had to admit, on cross-examination, that he knows practically nothing about such oils:

"Q. Do you know anything about petroleum oils, Doctor?

A. Practically nothing.

Q. Do you know how many different types of petroleum oils there are?

A. No." (Rep. Tr. 232; R. 58.)

The testimony of Dr. Carney concluded the government's case. It should be noted, in this connection, that *the government did not produce, as a witness in this cause, a single dissatisfied lay-user or medical user of Colusa Oil.* As the record plainly shows, this medical oil has been widely distributed to many users, and through many channels (doctors, drug stores, etc.) throughout the United States over a period of years. As this Honorable Court well knows, the agents of the Food & Drug Administration are widely distributed and omnipresent. It is common sense that, were Colusa Oil a "worthless" and "harmful" product, the Government would have produced at this trial a multitude of dissatisfied Colusa customers. In other words, the Government would not have been forced to rely upon such tenuous testimony as the aforementioned "expert" testimony.

Yet it failed to produce a single dissatisfied Colusa customer. *What an eloquent tribute to the efficacy of Colusa!*

PART TWO

Summary of Testimony of Dr. Frank O. Radovich (R. 124)

This witness, a graduate chemist (California Institute of Technology of Los Angeles, California), has specialized for over 15 years in the chemical phases of the petroleum industry (R. 124-125); his principal work during this period being the study and analysis of petroleum oils of of all types. Since 1936 he has been employed by the California Testing Laboratories of Los Angeles, California, and is now assistant manager of the Testing Laboratories. This concern is extensively engaged in research covering, and the testing and analysis of, petroleum oils, for the petroleum industry. Most of the oil companies are clients of this firm. (R. 125.)

Dr. Radovich testified that in the course of his work he had tested and analyzed oils from various parts of the United States as well as Mexico and Canada, and that:

> "There is no such thing as a typical crude oil. I have tested over 5000 and possibly 10,000 different crude oils in the course of my professional experience." (R. 126.)

He emphasized that Colusa Oil was an unusual type of this oil:

> "I said that this Colusa Oil was an unusual type of oil. I base that opinion on the various oils I have come across in the last 15 years. I have never found anything exactly like that crude oil in my own experience." (R. 132.)

He graphically described and illustrated the extreme complexity of petroleum. Taking a single series of the hydrocarbon family, he stated:

> "It has been calculated mathematically that in that simple designation there would be actually approximately 35 million different compounds, just with carbon and nitrogen alone, without any other substance." (R. 126.)

He also described the lengthy work being done by our government in its efforts to determine the constituents of a *single sample of petroleum oil:*

> "I am familiar with the American Petroleum Institute project carried on by the Bureau of Standards since 1934 on a mid-continent petroleum to determine the constituents existing therein. It was carried on by Dr. Washburn and Dr. Racini. After spending thousands of man hours in determining the constituents, they have identified approximately 50 or 60 different components of this one crude oil. They have work left to do for probably the remainder of their lifetime." (R. 126.)

The witness also mentioned the many and varied medicinal products derived from petroleum, with new ones being encountered right along, viz.:

> "There are a number of medicinal products made from petroleum oils, such as acetone, formaldehyde, chloroform, various glycols, phenols, carbolic acid, creosol and multitudinous others, and ichthyol, that is a manufactured product. And of course medicinal oils, vaseline and certain petroleum jellies." (R. 129.)

Dr. Radovich also testified at length regarding "ichthyol," the highly valuable drug produced by distilling certain crude oil shales in Austria. He testified that his firm had done extensive work for a client (Lewis Allen) in an effort to make ichthyol from crude oils in the United States. This work was done during the period 1937 to 1947. Many different crude oils were tested and used, and, finally, from crudes from certain limited areas in California, this laboratory was able to make commercial ichthyol, complying with the standards of the National Formulary, viz.:

> "After the original series of experiments, in 1941, 1942 and 1943, there was actually produced commercial ichthyol, the standard is the root, official name Ichthanmol. The National Formulary is a compilation of standards for proprietary compounds prepared by the Pharmaceutical group. The ichthyol that was

produced during the period I mentioned meets those standards. The ichthyol produced during that period was from oils in the United States, in about mid-California, Terra Bella and Devils Den fields. We went through a range of various oils, including shale oils from Colorado, the oils from Utah and various States that appeared to have peculiar property, which led us to believe that it might have been possible to produce ichthyol from." (R. 127.)

"The ichthyol we produced was sold as a commercial ichthyol, we certified to the analysis, to the weights and a certain formula. It was a dark, black viscous tarry material—its tarry appearance is characteristic of commercial ichthyol." (R. 127.)

He also testified in detail as to work done by the California Testing Laboratories for Mr. Allen to make ichthyol *using Colusa Natural Oil as a base* (R. 127-129). He testified that the resultant product (a sample of which he produced at the trial and which was introduced as Defendant's Exhibit 101) was an ichthyol type of product, even though it did not completely fulfill the requirement of the National Formulary:

"This product does not completely fulfill the specifications of the National Formulary, it is slightly deficient in sulphur." (R. 128.)

However, he very definitely expressed the opinion, based on his long work in this field, including his experiments with Colusa Oil, that with more time and research he could make ichthyol from Colusa Oil, viz.:

"From my experience it would be possible to manufacture ichthyol from this crude oil. We have made ichthyol from these other two crude oils in California. It has not been my experience that you can make ichthyol from all crude oils. The profession states very definitely that there are only certain types of crude oils and they do not name them or give you the characteristics to look for." (R. 128.)

"This is very close to National Formulary ichthyol. It is my opinion that with the proper amount of

research and time we could make true ichthyol from those, the first time we were closer than we usually come." (R. 128.)

Incidentally, this true scientist very candidly admitted that there are many things his science has yet to solve and learn:

"Petroleum scientists are not in accord as to what it is in ichthyol that has the supposed medicinal value, they don't know, I don't know." (R. 128.)

"We are learning new things every day in our laboratories, new products are being manufactured and new processes are being made." (R. 129).

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In the Supreme Court of the United States

OCTOBER TERM, 1949

No. 458

COLUSA REMEDY COMPANY, INTERVENER, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The finding of facts and conclusions of law of the United States District Court for the Northern District of Iowa (R. 9) are reported at 78 F. Supp. 721. The opinion of the United States Court of Appeals for the Eighth Circuit (C. R. 5) [1] is reported at 176 F. 2d 554.

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[1] The printed transcript of the record consists of three parts with respect to pagination, i.e. (1) the record filed by appellant in the court below, (2) the supplemental record filed by the appellee in the court below, and (3) the proceedings in the court below. The first part will be designated "R.", the second "S.R.", and the third "C.R."

JURISDICTION

The judgment of the Court of Appeals was entered on July 28, 1949 (C. R. 19). On October 20, 1949, the time for filing a petition for a writ of certiorari herein was extended by Mr. Justice Clark to and including November 18, 1949. The petition for a writ of certiorari was filed on November 17, 1949. The jurisdiction of this Court is invoked under 28 U.S.C. 1254 (1).

QUESTIONS PRESENTED

1. Whether this case is now moot, the drugs involved having been destroyed by the respective United States Marshals.

2. Whether the holding of the district court that the drugs involved were misbranded was justified by the evidence.

STATUTE INVOLVED

The pertinent parts of the Federal Food, Drug, and Cosmetic Act of June 25, 1938 (52 Stat. 1040, 1042, 21 U.S.C. 301, *et seq.*) read as follows:

> Sec. 301. The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is adulterated or misbranded. [21 U.S.C. 331.]
>
> Sec. 304 (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, * * * shall be liable to be pro-

ceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * * [21 U.S.C. 334.]

STATEMENT

This case arises out of libel proceedings which were instituted by the United States under Section 304(a) of the Federal Food, Drug, and Cosmetic Act, *supra,* in the United States District Courts for the Northern District of Iowa, the District of Colorado, and the Eastern District of Wisconsin for the seizure and condemnation of quantities of articles of drugs labeled in part "Colusa Natural Oil" and "Colusa Natural Oil Capsules" (R. 2-4, 7). Petitioner intervened as claimant (R. 4-5), and inasmuch as the charges contained in the several libels of information were substantially the same, the proceedings which had been instituted in Colorado and Wisconsin were, by stipulation of the parties and orders entered pursuant thereto under Section 304 (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334 (b)), transferred to the District Court for the Northern District of Iowa and consolidated for trial in that court (R. 7). At the trial of the case it was stipulated that petitioner had shipped the drugs involved in interstate commerce as alleged in the libels of information; that "Colusa Natural Oil" is a natural un-

refined petroleum; and that "Colusa Natural Oil Capsules" contains the same natural unrefined petroleum (R. 20-21). It was further stipulated that the label on the oil stated that that drug was "intended for use in treatment of Psoriasis, Eczema, Athlete's Foot and Leg Ulcers" (R. 21) and that the label on the capsules stated that they were "intended for internal use in treatment of Psoriasis, Eczema, Leg Ulcers" (R. 22). The labels on both the oil and the capsules indicated that the treatments should be continued "until skin is smooth and comfortable" (R. 21, 22). In addition to other evidence, the Government introduced the testimony of three qualified medical experts, who had treated with the oil and capsules several patients who were afflicted with the diseases specified in the labels. Basing their conclusions on that experience, they all testified that in their opinions neither the oil nor the capsules were an effective treatment for the diseases specified (Dr. Rostenberg, R. 35-43, S.R. 2-43; Dr. Trunnell, R. 48-52, S.R. 43-46; Dr. Carney, R. 52-59).

Petitioner introduced the testimony of several physicians and a number of lay witnesses, all of whom stated they had employed the oil and capsules as treatment for the diseases specified in the labels, and that the results were successful (R. 64-124, 135-146).

After trial the district court found that there was no credible or adequate scientific or medical foun-

dation for any claim or representation that "Colusa Natural Oil" or "Colusa Natural Oil Capsules" will cure the diseases specified in the labels placed on those drug articles, and that the said labelling was false and misleading (R. 13-14). The district court thereupon entered a decree directing that the quantities of the drugs seized in each of the consolidated cases be condemned as misbranded and be forfeited to the United States, and "that in each case the United States Marshal shall destroy such of the seized bottles of Colusa Natural Oil and Colusa Natural Oil Capsules which are in the control and custody of said Marshal" (R. 15-16).

On appeal the judgment was affirmed by the court below (C.R. 5-19). The mandate of the court below having issued, and no stay of execution having been sought, on August 29, August 31, September 1, and September 6, 1949, the quantities of drugs involved were, pursuant to the judgment of the district court and the mandate of the court below, destroyed by the marshals of the respective districts.[2]

ARGUMENT

1. These were *in rem* proceedings against the drug articles themselves. See *Hipolite Egg Co.* v. *United States,* 220 U. S. 45, 57. Since the decree of condemnation of the District Court provided for the destruction of the articles, and inasmuch as the decree has been executed by the destruction of the

[2] Certified copies of the Marshals' returns have been lodged with the Clerk of this Court.

said articles, the proceedings are at an end. The identical situation was involved in *United States v. 3 Unlabeled 25-Pound Bags Dried Mushrooms*, 157 F. 2d 722 (C.A. 7), where condemnation proceedings under the Federal Food, Drug, and Cosmetic Act had been instituted against mushrooms alleged to be adulterated. After trial, a decree of condemnation was entered. An appeal was taken to the Court of Appeals, but since no stay of the decree had been obtained by the claimant of the product, the Marshal destroyed it. In dismissing the appeal as moot, the Court of Appeals, per Minton, J., said:

> The continued existence of the mushrooms is essential to our right to proceed against the things themselves. The action is an action in rem. In such a proceeding, there is no party defendant. The goods stand to answer. They are the offenders. Day v. Micou, 85 U.S. 156, 162, 21 L. Ed. 860; National Bond & Investment Co. v. Gibson, D. C., 6 F. 2d 288, 290.
>
> The decree of the District Court goes against the mushrooms. The decree having been entered and executed, the proceeding is functus officio.
>
> Counsel for the Government readily admits the matter is moot here and counsel for the claimant reluctantly admits it is moot, but both parties ask us to decide the issue between them. This we decline to do. If we were to affirm the judgment, the District Court could not destroy the mushrooms. They have already been destroyed. If we reversed the judgment, there

> would be no mushrooms to restore to the claimant. The cause is clearly moot. We are not authorized to decide arguments but only "cases and controversies".

See also *Eureka Productions, Inc.* v. *Mulligan,* 108 F. 2d 760, 761 (C.A. 2), which arose under the customs laws.

It is clear, therefore, since the subject matter of this litigation has been destroyed, that the case is moot and no case or controversy exists under Article 3, Section 2, of the Constitution. See *United States* v. *Hamburg-Amerikanische Packetfahrt-Actien Gesellschaft,* 239 U.S. 466, 475-476; *St. Pierre* v. *United States,* 319 U.S. 41. Cf. *Fiswick* v. *United States,* 329 U.S. 211, 220-223. We submit that for this reason alone the petition for a writ of certiorari should be denied.

2. This case is a sequel to the injunction proceeding involved in *Chester Walker Colgrove and Colusa Remedy Co.* v. *United States,* No. 457 at this Term. The injunction in that case had the effect of requiring the Colusa Remedy Company to provide adequate directions for use in the labeling of the drugs "Colusa Natural Oil" and "Colusa Natural Oil Capsules." See *United States* v. *Colgrove, et al.,* 83 F. Supp. 880 (S. D. Cal.). To do this, the Company included in its labeling representations that the drugs were "intended for use in treatment of Psoriasis, Eczema, Athlete's

Foot and Leg Ulcers" and that the treatment should be continued "until skin is smooth and comfortable" (R. 21). Thereafter, the seizure actions involved here were instituted on allegations that the drugs were falsely represented as an effective treatment for psoriasis, eczema, athletes foot, and leg ulcers (R. 2-4).

Petitioner attacks the finding of the District Court that the labeling of the drugs was false and misleading, as alleged in the libels, on two grounds: first, because this finding was based solely on opinion evidence of medical experts; and second, because the court made this finding notwithstanding testimony of lay witnesses who had used the drug and testified that it was efficacious.

(a) The first ground of attack distorts the evidence presented through the Government medical witnesses. Each of these three witnesses was shown to be outstandingly qualified in the field of dermatology (Dr. Rostenberg, R. 36; Dr. Trunnell, R. 48; Dr. Carney, R. 52). Dr. Rostenberg, an Associate Professor of Dermatology and Assistant Director of the Allergy Unit of the University of Illinois College of Medicine (R. 36), testified concerning the causes, diagnosis, treatment, and prognosis of each of the diseases for which the drug was recommended. Based on his knowledge, training, and experience in the field of dermatology, he testified that the drug would not be an

effective treatment in the diseases for which it is recommended. (S. R. 7, 11, 17, 21.)

Dr. Rostenberg also treated five patients with this drug (S. R. 22) and on the basis of the inefficacy of the drug in the treatment of these patients, evaluated in the light of his knowledge, training, and experience in the field of dermatology, he testified that the drug was worthless in the treatment of the diseases for which it was recommended (S. R. 32-33). It is obvious that Dr. Rostenberg's opinions were based not alone on his general knowledge but also on ineffective results from the use of the drug on patients. Dr. Trunnell used this drug in treating seven patients (R. 48) and Dr. Carney treated six patients who were hospitalized at the University of Iowa Hospital (R. 53-56). Each of these patients was suffering from one of the diseases for which the drug was recommended. The testimony of these two doctors to the effect that the drug was not an efficacious or appropriate treatment for the conditions for which it was recommended was based on actual tests, the results of which they appraised in the light of their professional experience. (R. 56-57; S. R. 43.)

To say, as petitioner does, that the findings of the District Court were based solely on opinion evidence without evidence of observed results in the use of the drug is a misstatement of the facts.

Even if the medical witnesses called by the Government had never used the drug in actual tests their testimony as to its inefficacy would have

been sufficient to support the findings of the District Court. Fraud is not an element of statutory misbranding. An article of drug is misbranded if its labeling is false or misleading in any particular. Section 502(a), 21 U.S.C. 352(a). This is proved by showing that an incorrect statement was made. *United States* v. *One Device, Etc.*, 160 F. 2d 194, 200 (C.A. 10). This Court recently, in *Reilly* v. *Pinkus*, decided November 14, 1949, No. 31, at this Term, considered the scope of the holding in *American School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94, upon which petitioner relies. The following excerpt from the *Pinkus* opinion refutes petitioner's contention as to the sufficiency of expert medical opinion to support a finding of misbranding (slip opinion, p. 4):

> The contention seems to be that even the testimony of the most experienced medical experts can never rise above a mere "opinion" unless the expert has made actual tests of the drug to determine its effects in relation to the particular representations alleged to be false. The *McAnnulty* holding did not go so far. *We do not understand or accept it as prescribing an inexorable rule that automatically bars reliance of the fact-finding tribunal upon informed medical judgment every time medical witnesses can be produced who blindly adhere to a curative technique thoroughly discredited by reliable scientific experiences* [italics supplied].

It is settled by many Court of Appeals' decisions that a qualified physician may give his opinion as

to the efficacy or lack of efficacy of curative agents, regardless of whether he has had actual experience with the particular article, and that such testimony constitutes sufficient evidence to support a finding concerning the efficacy of the article.[3]

(b) Lay users called by petitioner at the trial testified that they had used the drug for the treatment of skin conditions and that it relieved the conditions, and in some cases they believed their ailment was cured. Petitioner seems to argue that the testimony of these fourteen laymen required a finding that the drug was efficacious in the disease conditions for which it was recommended. This position is untenable.

The satisfied lay users were not permitted to diagnose their conditions or give hearsay testimony as to what doctors had told them with respect to their diseases. They were permitted to describe their symptoms and sufferings. The District Court admitted this testimony and recognized that the question of the weight of such testimony was a matter for its determination. (R. 63.)

In weighing the testimony of these lay witnesses, the District Court might have considered that "the proneness of lay patients to err in accrediting responsibility for benefits to health is well under-

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[3] *Research Laboratories* v. *United States*, 167 F. 2d 410, 416 (C.A. 9). certiorari denied, 335 U.S. 843; *United States* v. *One Device, etc.*, 160 F. 2d 194, 199 (C.A. 10); *Irwin* v. *Federal Trade Commission*, 143 F. 2d 316, 324 (C.A. 8); *John J. Fulton Co.* v. *Federal Trade Commission*, 130 F. 2d 85, 86 (C.A. 9), certiorari denied, 317 U.S. 679; *Charles of the Ritz Distributors Corp.* v. *Federal Trade Commission*, 143

stood." *Federal Trade Commission* v. *Kay*, 35 F. 2d 160, 162 (C.A. 7). The District Court might also well have been of the view expressed in *United States* v. *50¾ Dozen Bottles* * * * *Sulfa-Seb*, 54 F. Supp. 759, 762 (W. D. Mo.):

> The nature of the simplest disease is so obscure to a layman that his conclusions touching what will benefit it and what will not benefit it mean little.

The District Court made clear its view that in a case of this type testimony from qualified experts is the more satisfactory type of evidence (R. 63).

We submit that the Court of Appeals correctly ruled that "the question whether the labeling on a drug is 'false and misleading in any particular' is a question of fact, and the test to be applied is whether the drug is effective in curing, or giving relief from, the disease for which it is recommended" (C. R. 18). See also, *United States* v. *Six Dozen Bottles* * * * *Dr. Peter's Kuriko*, 158 F. 2d 667 (C.A. 7); *United States* v. *Kaadt*, 171 F. 2d 600 (C.A. 7). On this point the evidence was conflicting. As has been shown there was substantial credible evidence to support the findings of the District Court and it cannot be said that its findings were clearly erroneous.

F. 2d 676, 678 (C.A. 2); *Neff* v. *Federal Trade Commission*, 117 F. 2d 495, 497 (C.A. 4); *Dr. W. B. Caldwell Inc.* v. *Federal Trade Commission*, 111 F. 2d 889, 891 (C.A. 7); *Goodwin* v. *United States*, 2 F. 2d 200, 201 (C.A. 6).

3. Petitioner also contends that Findings 17 and 18 (R. 13) with respect to the meaning of the labeling were unjustified. The labels on which these findings were based are set out in Findings 6 and 7 (R. 10).

This Court said in *United States* v. *Ninety-Five Barrels * * * Vinegar,* 265 U. S. 438, 442:

> It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.

The meaning of labeling is a question of fact. *United States* v. *7 Jugs * * * Rakos,* 53 F. Supp. 746, 759-760 (D. Minn.), and cases cited. Labeling must be considered in its entirety and the language used is to be given the meaning ordinarily conveyed by it to those to whom it is addressed. *Aronberg* v. *Federal Trade Commission,* 132 F. 2d 165, 167 (C.A. 7); *Hall* v. *United States,* 267 Fed. 795, 797 (C.A. 5).

Petitioner concedes that the label represented that the product would alleviate or relieve in the treatment of the diseases named on the label (S. R. 46). Since the drug was not offered for palliative relief only, and since there was no exception of any ailment embraced within the classes named, it was proper for the District Court to find that the representations were made with respect to the named diseases "of all types and kinds at all stages thereof" (R. 13) *Hall* v. *United States,* 267 Fed.

795 (C.A. 5.) The court might well have found that the statement, "Continue treatment until skin is smooth and comfortable," taken with the rest of the label, represented that continued use of the oil would effect a cure.

This Court said in *Federal Trade Commission* v. *Standard Education Society,* 302 U. S. 112, 116:

> The fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced. There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. * * *

We submit that the findings of the District Court as to the meaning of the labeling were warranted and that there was no error in the ruling of the Court of Appeals in upholding these findings.

4. There is no merit in petitioner's claim that the courts below applied an erroneous rule as to the degree of proof required. It is the Government's position that in a seizure action under the Federal Food, Drug, and Cosmetic Act it is required to prove its case by a preponderance of the evidence. We believe that *C.C. Co.* v. *United States,* 147 F. 2d 820, 824 (C.A. 5), with its detailed rationale and citation of authorities expresses the correct view as to the degree of proof in such ac-

tions. Accord: *United States* v. *One Device, etc.*, 160 F. 2d 194, 199-200 (C.A. 10). It is true that in *Van Camp Sea Food Co.* v. *United States*, 82 F. 2d 365 (C.A. 3), a case decided under the Food and Drug Act of 1906, 34 Stat. 768 *et seq.*, it was held that the Government had the burden of proving by clear and satisfactory evidence that a product was adulterated. The *C.C. Co.* case points out that that idea was based upon the premise that the earlier Act should be strictly construed because it provided for forfeiture of property. This Court, however, in *United States* v. *Dotterweich*, 320 U. S. 277, has held that the high purposes of the Federal Food, Drug, and Cosmetic Act require that it be given a liberal construction.

So far as the instant case is concerned, it is purely academic to consider what is the proper rule as to the degree of proof required. Neither of the courts below thought that the Government is required to establish its case only by a preponderance of the evidence. The District Court found (Findings 19-20, R. 13-14) that "there is no credible or adequate scientific or medical foundation for any claim or representation that Colusa Natural Oil" will cure, or alleviate, or give relief from, or assist in the treatment of the diseases named on the labels. The court further found that the drug in question "is worthless or without value in the treatment of any or all of said diseases at any stage thereof." These findings of fact will not be set

aside unless clearly erroneous. Rule 52(a), F. R. Civil P. If these findings of fact stand, the conclusion is inevitable, by any standard of proof, that the labeling of the drugs was false and misleading. The Court of Appeals' opinion (C. R. 8-10) carefully and accurately states the applicable law on this point.

CONCLUSION

The drugs involved having been destroyed, the case is now moot. Furthermore, the decision of the court below is correct, and the case warrants no further review. It is respectfully submitted, therefore, that the petition for a writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1949

COLUSA REMEDY COMPANY, INTERVENER, *Petitioner*,

v.

UNITED STATES OF AMERICA.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit.

PETITIONER'S REPLY TO THE BRIEF OF UNITED STATES IN OPPOSITION.

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Dated: December, 1949.

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In its brief in opposition, the Government has suggested that the case is moot because the bottles of oil involved in the seizure have been destroyed. Petitioner respectfully submits that either (1) the case is not rendered moot by reason of the destruction of the bottles, or (2) if it has been so rendered moot, the Court should grant certiorari and reverse the judgment of the court below in order that that judgment should not stand as *res judicata* against petitioner.

1. *The destruction of the bottles has not rendered the judgment below moot.*

> *This case and the findings herein are of vital importance to appellant because if and when they become final they will be urged as res judicata on the issue as to the the efficacy of Colusa Oil in the treatment of the skin diseases involved in this case.*

In fact, the judgment and findings in this cause have already been so urged and relied upon by the government in the U. S. District Court at Los Angeles in a proceeding involving this same oil and this same issue and party (*U. S.* v. *Colusa Remedy Company*, No. 8572 WM-Civil, U. S. District Court, Southern District of California, Central Division).

In other words, the mere destruction of the drugs below does not render the cause moot.

The authorities are clear that where a judgment or findings may have some future significance directly affecting the rights of the parties, the cause cannot be said to be moot. The following are cases pertinent to this point:

Southern Pacific Co. v. *Interstate Commerce Commission*, 219 U. S. 433, 31 S. Ct. 288, 55 L. Ed. 283.
Southern Pacific Terminal Co. v. *Interstate Com. Com.*, 219 U. S. 498, 31 S. Ct. 279, 55 L. Ed. 310.
U. S. v. *Trans-Missouri Freight Assn.*, 166 U. S. 290, 17 S. Ct. 540, 41 L. Ed. 1007.
Howard v. *Wilbur* (6 Cir.-1948), 166 F. 2d 884.
Kaufman v. *Mastin*, 66 W. Va. 99, 66 S. E. 92.
Sinquefield v. *Valentine*, 159 Miss. 144, 132 So. 81.

In *Southern Pacific Co.* v. *Interstate Commerce Commission* (supra), the Supreme Court of the United States refused to dismiss an appeal, although the defendant association, under which the defendant railroads illegally fixed rates, was dissolved prior to the appeal. On the question of dismissal of the appeal upon the ground that the questions therein had become moot, the Court said:

> "* * * it is to be observed that clearly the suggestion is without merit, in view of the possible liability for

> reparation to which the railroads might be subjected if the legality of the order were not determined; *and the influence and effect which the existence of the rate fixed for two years, if it were legal, would have upon the exercise by the railroads of their authority to fix just and reasonable rates in the future, clearly causes the case* to involve not merely a moot controversy." (Emphasis ours)

The case of *Southern Pacific Terminal Company* v. *Interstate Commerce Commission* (supra), decided at the same time as the above case, is another clear cut case to the same effect.

In the case of *Howard* v. *Wilbur* (supra), the circuit court of appeals notes the many exceptions to the general rule, and, insofar as the discussion in that case is pertinent to the instant case, we quote from the opinion as follows:

> "There is another possible exception to the general rule to the effect that although the issue is moot in the particular case before the court, yet the appeal is not treated as moot where if the judgment is not reversed a party will be precluded from establishing facts which may be vital to his rights in other proceedings. Such an exception seems to have been recognized in *Kaufman* v. *Mastin*, 66 W. Va. 99, 66 S. E. 92, 25 L. R. A., N. S., 855; *Sinquefield* v. *Valentine*, 159 Miss. 144, 132 So. 81, 76 A. L. R. 238."

In the case of *Kaufman* v. *Mastin* (supra), which is cited in *Howard* v. *Wilbur* (supra), the West Virginia Court refused to dismiss an appeal evidently in order to prevent the judgment below becoming res adjudicata to the prejudice of the defendant.

To similar effect is the case of *Sinquefield* v. *Valentine* (supra), also cited in *Howard* v. *Wilbur* (supra), where it appeared that the requested dismissal and refusal to reverse would have left the petitioner in a position where he could not assert his rights.

2. *If the judgment has been rendered moot by the destruction of the bottles, this Court should grant certiorari and reverse.*

It is the well-established practice of this Court that if a judgment has been rendered moot before all appeals have been exhausted, the judgment is not conclusive in a subsequent action. To make this certain, this Court has followed the practice of reversing the judgments of the lower court so that there will be no possibility that the judgment will be regarded as *res judicata.* The very case cited by the Government in support of its plea of mootness, *United States* v. *Hamburg-Amerikanische Packetfahrt-Actien Gesellschaft,* 239 U. S. 466, (at page 7 of the Brief in Opposition), held that reversal of the judgment below was required. Similarly see *U. S.* v. *American-Asiatic S. S. Co.,* 242 U. S. 537 (1917); *Commercial Cable Company* v. *Burleson,* 250 U. S. 360 (1919); *Danciger Oil & Refining Company* v. *Smith,* 290 U. S. 599 (1933). More recently see *SEC* v. *Long Island Lighting Co.,* 325 U. S. 833 (1945) and *SEC* v. *Engineers Public Service Co.,* 332 U. S. 788 (1947).

It should be noted that the Government took the action of destroying the bottles before the time for petitioning for certiorari had expired. No reason or justification is given for this action, taken *without notice.* The Government should not be permitted to deprive petitioner of its right to petition this Court for certiorari and at the same time preserve for itself the benefit of the judgment of the court below as *res judicata.*

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3. In the case of *Reilly* v. *Pinkus,* 70 S. Ct. 110, decided November 14, 1949, after the petition for certiorari in this case was printed, the court enforced a fraud order in connection with medical advertising. But in doing so it re-

affirmed the *McAnnulty*[1] decision on which we rely, speaking as follows:

> "But we do accept the McAnnulty decision as a wholesome limitation upon findings of fraud under the mail statutes when the charges concern medical practices in fields where knowledge has not yet been crystallized in the crucible of experience. For in the science of medicine, as in other sciences, experimentation is the spur of progress. It would amount to condemnation of new ideas without a trial to give the Postmaster General power to condemn new ideas as fraudulent solely because some cling to traditional opinions with unquestioning tenacity." (70 S. Ct. 110, 113)

The case at bar comes within this statement of principle. We have a large amount of clear cut factual data (human experiences and reactions in the use of the oil as well as testimony of medical practitioners) in favor of Colusa. The Government's meager case consists essentially of the opinion testimony of only three medical doctors.

CONCLUSION.

Accordingly we submit (1) that the case is not moot, (2) that if it is moot, the Court should grant certiorari and reverse the judgment below, and (3) that the judgment below is contrary to the principle recently announced in *Reilly* v. *Pinkus* (supra).

Respectfully submitted,

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[1] *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94.